S. Hrg. 103-258

NATIONAL ACADEMY OF SCIENCES REPORT ON PESTICIDES AND CHILDREN

Y 4. AG 8/3: S. HRG. 103-258

National Academy of Science Report...

HEARING

BEFORE THE

COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY UNITED STATES SENATE

ONE HUNDRED THIRD CONGRESS

FIRST SESSION

ON

NATIONAL ACADEMY OF SCIENCES REPORT ON THE HEALTH RISKS ASSOCIATED WITH PESTICIDE RESIDUES FOUND IN THE DIETS OF INFANTS AND CHILDREN, FOCUSING ON RECOMMENDATIONS FOR A HEALTH-BASED STANDARD FOR PESTICIDE TOLERANCES

JUNE 29, 1993

Printed for the use of the
Committee on Agriculture, Nutrition, and Forestry

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THE NATIONAL ACADEMY OF SCIENCES REPORT ON PESTICIDES AND CHILDREN

TUESDAY, JUNE 29, 1993

U.S. SENATE,
COMMITTEE ON AGRICULTURE, NUTRITION, AND FORESTRY,
Washington, DC.

The committee met, pursuant to notice, at 10:07 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Patrick J. Leahy, chairman of the committee, presiding.

Present or submitting a statement: Senators Leahy, Daschle, Feingold, Lugar, Cochran, Grassley, and Craig.

STATEMENT OF HON. PATRICK J. LEAHY, A U.S. SENATOR FROM VERMONT

The CHAIRMAN. Good morning. I appreciate everyone being here, especially my colleague, Senator Kennedy, who I know has changed his own schedule around so he could be here this morning.

I should note at the outset that this hearing is not about whether children should eat their vegetables. They should. That is a battle parents have been fighting for years. I know I did it with my own children when they were growing up, and scientists or Senators aren't going to settle that. I didn't settle that issue, either, in my capacity as a father or as a U.S. Senator. Children should eat their vegetables.

And the hearing is not really about whether or not our food supply is safe. We know that the United States has one of the safest food supplies in the world.

The question really is a very simple one. Do EPA's current policies adequately protect our children?

The National Academy of Sciences has now released the report on pesticides and children that I requested back in 1987 and I got the funding for in 1988. Their report has confirmed many of my original concerns. I believe it has made the administration take notice.

When I requested the report and sought the funding for it, I asked the National Academy to prepare this report to identify toxicological issues of greatest concern, clarify what is known about exposure to pesticide residues in the diets of infants and children, make recommendations on ways to improve the current risk assessment process, and identify research priorities.

Children exposed to pesticides early in life may be at a greater risk of cancer. The timing of exposure can be critical, and we should not and cannot underestimate that risk.

Toxicity of chemicals is different in children and adults. If you do a test on adults, that is no way to predict what it might be for a child. That is simple common sense and this study has borne that out. Children are exposed to multiple pesticides with a common toxic effect, a factor not included in current risk assessment methodologies.

FDA does not target pesticide testing to those foods most often eaten by children, something we ought to be aware of. Only four of the most commonly consumed foods are found on the list of FDA's 18 most commonly tested foods.

EPA, I believe, should base its tolerance-setting process more on health considerations than agricultural practices. That really is the function of FDA, to look at health considerations. Children should be able to eat a healthful diet containing legal residues without encroaching on safety margins.

We need better testing procedures. We have to specifically evaluate toxicity to infants and children. That is not being done. Estimates of expected total exposure to pesticide residues should reflect unique diets of infants and children and should account for all nondietary intake of pesticides.

I think as the problems become more clear the concerns become more immediate. I have been pushing for a reduction in farm use of pesticides for almost two decades, and I am finally heartened by the support from the White House. This is the first administration in my 19 years here that has been willing to state publicly that farmers can reduce pesticide use and move toward more sustainable farming methods.

Actually, that can be good news to the farmers. They are the ones who are exposed first to the pesticides, ahead of anyone else, and they are also the ones that have to bear the cost of it. I have said many times that the problem with our pesticide laws is they leave the public in the dark and they leave the farmer on the hook.

The public is in the dark because safety studies on many pesticides have not been completed. Consumers will not be satisfied with our food safety laws if it takes years for EPA to remove harmful pesticides from the market when it decides that they are harmful. And the present system also does not work for farmers. As new health data comes to light, they don't know from year to year whether they will be able to use a pesticide or not. They can't make the necessary planning.

With this new information, the administration has joined my effort by announcing the principles on which it will base its new pesticide policies. It is a landmark statement of policy. It has the promise of breaking the gridlock on pesticide issues, and moving to a new system that makes sense both for farmers and for the consuming public.

As I told the White House several weeks ago, we must have a process where we identify which pesticides could pose the greatest problem and dedicate Federal resources to finding alternatives so that farmers can continue to produce the quantity and types of food that our diets demand. So I am happy to see that the new policy accepts this premise.

This year we have to reform our pesticide laws based on scientifically sound standards. We must be sure that we protect our most

sensitive population—our children—and if we protect our children then everybody wins.

Children should eat healthy food. Parents shouldn't have to wonder whether they are putting their children at risk. Which one of us as parents want to have any question in our mind when we feed our children, when we tell them what to eat? We don't want to have a question in our mind that we may be putting them at risk. And farmers should know that they have pest control strategies that work.

It is really very simple, and I hope that is where we may go.

Senator Lugar has advised me, because of another commitment, that he is going to be late arriving.

I wonder, gentlemen, whether any of you have anything to say before we hear from Senator Kennedy.

STATEMENT OF HON. LARRY E. CRAIG, A U.S. SENATOR FROM IDAHO

Senator CRAIG. Mr. Chairman, yes.

Thank you for a timely hearing immediately following the release of this long-awaited report. I say that because it appears to be about 3 years late and there has been a considerable amount of speculation as to why it is late. Let me conclude that in asking that question we found out that in many cases the Academy had to completely rework sets of data that it received from Federal agencies who were cooperative and cooperating agencies in assembling the necessary information from which they drew their conclusions.

So I can draw a conclusion from that that even with what we have, sometimes we are ill-prepared to analyze it and/or effectively respond to it. Hopefully this effort and the effort of the Academy begins to set forth a framework that is a much more reasonable and measurable approach toward giving accurate and responsible data so that proper decisions can, in effect, be made.

I have read the executive summary, although I have not read the complete report. I am pleased that they have discovered that children aren't adults, nor are they even small adults, but they are in fact children and children are much different than adult human beings, and we have known that for a long time. I am glad that it has now been concluded.

I say that not in cynicism but the fact that from that base of information maybe we can go forth and draw some reasonable conclusions and provide some policy and direction that creates some balance, both in the productive sector of our economy and in the consumptive sector. Both are important.

Your statement is extremely valuable. I think all of us are concerned. We all want to do the right thing, but we want to make sure the policy doesn't destroy the phenomenally productive economy that has made this country what it is today, and that is agriculture. We also know that production agriculture must have tools to work with.

But you are right. I am a former farmer and rancher and I want to make darn sure in the application of herbicides, pesticides, and insecticides that they are done right, they are done properly, that

there is little to no residue, and that it is in the safe margin, not just for adults but for children.

I hope that from this effort, from your effort starting back in 1987 we can move forward with the formation of consistent policy that is workable and livable, practical, and that applies science—let me underline that—and that applies science and not politics to this issue.

I look forward to those who are testifying.

The CHAIRMAN. Thank you very much, Senator Craig, and thank you for the kind words.

Senator Grassley, do you have a statement?

STATEMENT OF HON. CHARLES E. GRASSLEY, A U.S. SENATOR FROM IOWA

Senator GRASSLEY. Mr. Chairman, I thank you very much for calling this very important hearing. And while it might be true that in this committee or even in the entire Senate we may disagree from time to time and quite passionately sometimes about a great many things, the health of this Nation's children is a subject on which we all agree is very important.

No one would dispute that the diet of our children and how it affects their health deserves study and, if necessary, action. As this study reveals, average adult consumption along the regulatory standard may be an imperfect means by which we gauge the health of our children. This study, I hope, will be the first step in fully understanding how pesticides impact this Nation's youth.

I am a farmer from a primarily agricultural State, and I know first hand the benefits that agricultural inputs have provided not only for this country but also for feeding the hungry of the world. In part because of pesticides, the United States is the production envy of the world, an unparalleled producer of cheap and safe food. In part because of pesticides, many countries around the world are now able to feed themselves.

But I also happen to be a father and I also happen to be a grandfather, and I know that agricultural productivity should not be the overriding criteria by which we evaluate pesticides. I am concerned that we know full well what our children eat and how it will affect them. I hope that a scientific analysis of this issue will forge a rational consensus on this problem and circumvent the hysteria that has marked similar issues in the past.

I look forward to reviewing the findings of the report.

Secretary of Agriculture Espy will be in Iowa and Minnesota and South Dakota and Nebraska tomorrow. He will be looking at the flood damage that has been done there. He will also see some fields that are producing, but he will also see a lot of fields that will be green, will be unable to use mechanical cultivation because of the wet and the mud.

In my own situation, just Saturday we are still putting beans in, a month late. Ideally, it ought to be done on May 25th. We are still putting them in. Without an early frost, we may get a crop this year. But as I was disking those fields, preparing them for my son to seed the beans, and you couldn't go all the way across the field because of the wet spots in some of them and we got stuck on occa-

sion and would have to pull each other out, but let me say, as I saw some parts of our field growing a crop of corn with a massive amount of grass in it, there is no way even if you could mechanically cultivate that that you would kill the grass and still get a crop.

So don't forget in some instances way beyond the control of the average farmer you are going to have to allow alternatives that include the use of pesticides if we are going to have food production.

Mr. Chairman, I yield.

The CHAIRMAN. Thank you very much.

Senator Kennedy, I appreciate your being here and I also appreciate your changing the time of your own hearing to be able to accommodate our schedule. I am glad to have you here, sir.

I should also note for the record that when I came to the United States Senate 19 years ago, this was an area where Senator Kennedy had already taken the lead and already pushed on, so I am especially pleased that he is here.

STATEMENT OF HON. EDWARD KENNEDY, A U.S. SENATOR FROM MASSACHUSETTS

Senator KENNEDY. Mr. Chairman, let me acknowledge what the other members of the committee have acknowledged, that after the 1987 report on The Delaney Paradox, which was produced by the Academy of Sciences, that you were the originator and the driving force in the Congress and the Senate of the United States for the development of this report and it is only because of your perseverance and persistence that all of us in the Congress have the benefit of this particular information, which hopefully can be the basis of further action.

I think all of us who are concerned about health, all of us who are concerned about children's health, all of us who have been awakened to the various challenges as a result of the Nation's sensitivity to environmental issues and environmental health know that you have really been the leader in this area and we certainly look forward to continuing to work with you and the members of the committee on this issue.

The Academy's study does provide a road map to long overdue reforms that will finally resolve the uncertainties over whether the food supply is as safe as it should be for children. No longer can it be credibly argued that a food safety system that is geared to adults provides the needed safeguards for children.

And I think, as has been mentioned by all the members of the committee, the particular sensitivity of children has been really a part of the development on the questions of the dangers of health for our children as the result of pesticides, herbicides, and fungicides. The fact that children eat a more limited amount of food product and generally those food products have been affected by the pesticides, the fact that the children's body weight in relationship to the amount that is actually consumed, can have and does have an important impact on the children. The fact that many of their whole systems are still developing makes them particularly sensitive, and is something that we have to be particularly attuned to.

As I pointed out, in 1987 the Academy conducted the other study on pesticides, The Delaney Paradox, which became a major advance in our understanding of pesticides and food, and the current report will serve as an equally important resource.

At the core of the Academy's finding is a fundamental recommendation that would seem to be self evident. But in the Alice-in-Wonderland world of pesticide regulation, it is a revolutionary concept, that the legal limits of pesticides in food should fully protect human health, including the health of infants and children.

Most Americans probably assume that this is the law today, but it is not. In spite of years of regulation, the legal limits on pesticide residue on raw agricultural products are still based on the levels likely under normal agricultural practices, not on the levels necessary to assure no harm to adults or children.

The current regulatory regime is plagued by loopholes that permit dangerous chemicals to remain on the market because of vague cost-benefit analyses that undercut the goal of protecting the public, usually children.

The Academy proposes a health-based standard for pesticide tolerance. It also strongly emphasizes that we cannot be confident that a pesticide level safe for adults is also safe for children.

We have known for some time that children may receive a disproportionate share of their lifetime cancer exposure at an early age. The Academy's report provides new analytical tools to assess the scope of these cancer risks and prevent front-end loading of the risk for children. Clearly, the current risk assessment techniques used by the Environmental Protection Agency do not adequately address the health effects of pesticide residues on children.

Congressman Waxman, who is here today, and I have already proposed a children's standard in the pesticide reform legislation that we have introduced this year. The Academy's recommendations give strong support to this proposal, and I look forward to early action by Congress to implement it.

A related issue is also central to the findings of this report. Limitations in the available quality of data on food consumption, pesticide use, and pesticide toxicity affect our ability to adequately protect the food supply. For too long, this lack of information has been an excuse for failing to safeguard the public. It is unacceptable that it takes so many years to resolve these basic questions. The legislation that Congressman Waxman and I proposed would require the development of much of the information called for in the Academy's report.

If fundamental questions like this about safety cannot be answered with respect to particular pesticides, those pesticides should not be allowed on the market. It is time to stop gambling with children's health.

The protection of children is one aspect of a much broader effort to promote the development of less toxic agricultural pesticides. Safer pesticides and new pest-resistant varieties of crops are being developed by sophisticated research techniques in biotechnology. Other ways to reduce these risks include innovative farm cultivation techniques and alternative pest control methods that do not involve the use of pesticides.

Greater public confidence in the food supply will serve the interests of farmers, the food industry, chemical manufacturers, and consumers. We can no longer accept pesticides as usual. The National Academy's report provides a challenge to Congress and the administration to take action that is long overdue. I think all of us welcome the Clinton administration's statement in the recent weeks to move in this direction and to recommend to work with the Congress in this area.

We have a unique opportunity to enact real pesticide reform in this Congress, and I look forward to working with the members of this committee to achieve it.

Mr. Chairman, we had in 1991 in our Health Committee a committee hearing on the issue of children's health and the impact of the pesticides, and Dr. Jackson, who is here, testified and provided enormously useful and helpful information. I think we have expanded our interest to recognize that we are not only talking about cancer. And as the father of a child that developed cancer, I have a particular sensitivity to that, but also the neurotoxic implications that I think have been raised as well in the course of this report, and that obviously is enormously important.

Finally, let me just say that I don't know whether I am speaking prematurely but I have welcomed almost the quietness of the reaction of the industries that would be affected by this. I think, generally speaking, there has been some constructive and positive statements that they have made, and I think that that is enormously important if we are going to try and find some common ground. We want to try and find ways of really working together.

I know this hearing was actually scheduled to receive the report, which has already been prereleased, but I do think that that may be some indication of the willingness to try and find some common thoughts that we can make some progress. We will certainly hope to do that, working closely with you and the members of this committee in this extremely important area.

The CHAIRMAN. Thank you, Senator Kennedy.

I would echo also what you have said about the industry. I think we all know we have the safest food in the world here, but I have heard from a number of members of the industry saying if we have ways to make it safer, let us work for it. I think that is a very positive attitude.

We all speak of children, either our own or our grandchildren or others. I still think of being on a farm in Vermont with a family I know very well, wonderful children, and having the farmer tell me, just talking generally about this area of pesticides. He said, "You know, I wish they would look into these things a lot more." And then pointing to his own children he said, "You know, they are the ones who help me put the pesticides down, and I am never absolutely sure whether I can trust what I read on the labels."

I think that we have to remember that these are the people who are the first in the chain of using them, but each one of us when we buy food for our families want to know it is safe.

So Senator, I thank you very, very much for being here. I think we are going to actually have you out of here in time for your committee meeting. I appreciate it very, very much.

Senator KENNEDY. I thank you very much. Thanks to the committee.

The CHAIRMAN. We are very fortunate to have Congressman Henry Waxman, who is a chair of the Subcommittee on Health and the Environment in the House and also a good personal friend.

Congressman Waxman, I appreciate your taking the time to come over here because, again, you have been one who has labored so long and hard and consistently on this issue. It is an honor for us to have you here.

STATEMENT OF HON. HENRY WAXMAN, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Mr. WAXMAN. Thank you very much, Mr. Chairman. I appreciate your very kind words.

I want to commend you for holding this hearing and for requesting the report which is the subject for the hearing today. I believe that this report is an important one on the issue of childhood exposure to pesticides in food, and the National Academy of Sciences has done an excellent job in giving us what I think is a watershed in the history of pesticide regulation. I look forward to working with the members of this committee to implement its recommendations.

According to the study, the bottom line is that our children are at unnecessary risk from pesticides in food. The report finds that pesticides can injure children, that a significant number of children are exposed to unsafe pesticide levels, and that we are not doing enough to protect our children. We must do better.

The report restates some fundamental points. The exposure of children to pesticides is greater than adults because relative to their body weight they eat larger quantities of fruits and juices. Children are uniquely vulnerable to some pesticides because their nervous systems are still developing.

The report is also a stinging indictment of each of the three agencies that shares the responsibility for regulating pesticides. In order to know the risk of pesticides to children, we need to know what children eat and how much, but the report tells us that the USDA food consumption survey does not collect adequate information to evaluate consumption patterns among children.

In order to know the risk of pesticides to children, we need to know how much pesticide residues are left on food, but the report tells us that the FDA's residue detection program does not provide us with sufficiently reliable information to make this evaluation.

In order to protect children from the risks of pesticides, we must have in place a regulatory system that is designed to shield children from excessive pesticide exposure, but the report tells us that EPA's tolerance-setting program is deficient in a number of respects.

First, EPA concentrates on average pesticide exposures. EPA does not look at subgroups, such as children. EPA does not protect children subject to high exposure of pesticides.

Secondly, EPA looks at one pesticide at a time. It does not consider the cumulative effects of pesticides.

And finally, once EPA has identified a risk, it weighs that risk against the economic benefits of the pesticide to farmers. According to the report, EPA has allowed agriculture interest to predominate over public health. This is unacceptable, especially where our children are concerned. We must protect our children from pesticides that may jeopardize their health.

Mr. Chairman, this report was produced by a bipartisan group of scientists with impressive credentials. Outside their participation in this project, some of the panel's members tend to lean towards industry and some of its members tend to lean toward agricultural interests, but they came together and after 5 years of study reached a consensus on this very important issue of the risks to our children from pesticides.

Mr. Chairman, as you know, during each of the past three Congresses Senator Kennedy and I have introduced legislation to revise the regulation of pesticides. That legislation would (1) establish a special standard to protect children from pesticides, (2) require EPA to set health-based pesticide standards for both children and adults, eliminating economic costs as a relevant consideration if the pesticide is found to have a significant risk, (3) reform EPA's procedures so that the agency would be required to take into account cumulative exposures to pesticides, including exposure to drinking water, (4) streamline EPA procedures and (5) establish deadlines so that EPA must make timely decisions on the safety of pesticides on the market, considering the most risky ones first.

These provisions closely parallel the recommendations in the National Academy of Sciences report. Senator Kennedy and I intend to reevaluate the legislation in light of this report to identify any additional statutory changes that may be necessary.

In conclusion, I want to say that this report is a wake-up call to all of us. It is all too easy to become complacent about a danger that is common and to which we are exposed everyday.

But Mr. Chairman, the danger from pesticides is different from many other dangers because we have the opportunity to do something about it if we enact legislation to reduce the use of the most dangerous pesticides to which we and our children are exposed.

I look forward to working with members of this committee on this very important issue, and I thank you for the opportunity to have me present this testimony today.

The CHAIRMAN. Thank you very much, Chairman Waxman.

I think you and I and members of this committee and your committee will probably be spending a lot of time together this summer on it. I know that you have a number of other commitments in the House, and I appreciate your being over here. Thank you very much.

Mr. WAXMAN. Thank you, Senator.

The CHAIRMAN. I also see Congressman Richard Lehman from California is here. Again, Congressman, I want to thank you for taking the time to come over. I know that you also have a number of concurrent commitments in the other body, and I appreciate your taking the time to come here, sir.

STATEMENT OF HON. RICHARD H. LEHMAN, A REPRESENTATIVE IN CONGRESS FROM CALIFORNIA

Mr. LEHMAN. Thank you very much, Mr. Chairman.

I certainly appreciate the opportunity you have given me today to come here and testify on this very important subject.

Regrettably, because they are otherwise engaged, Congressmen Rowland and Bliley, the other major sponsors of our food safety legislation, can't be here this morning. However, I would like to respectfully request that their testimony, which I have, be included in the record.

The CHAIRMAN. It will be included following yours, sir.

Mr. LEHMAN. Thank you.

Mr. Chairman and members of the committee, I represent the richest agricultural area in the world, the San Joaquin Valley of California. California offers a variety of fruits and vegetables with many commodities that are only grown in our State.

I grew up on one of those farms, so I can bring you first-hand knowledge of how chemicals are used in the real world. I can tell you we have come a long way since I was a kid, when my father and I used to get the old spray rig out, dump the stuff in it, and go through the vineyard for the afternoon applying the product. Today it is certainly a lot different, a lot more controlled than that was many years ago.

I can assure that the agricultural community which I know stands committed to constantly improving its techniques and practices to ensure the safest food supply possible.

As a lead sponsor of major food safety reform legislation, I also want to commend the National Academy of Sciences for their hard work and diligence in bringing this important study, "Pesticides in the Diets of Infants and Children," to fruition. The report is well balanced and is a credible assessment of what we can do to ensure that children are well protected in their eating habits.

The most important point to acknowledge is that we have some of the highest standards and at the same time lowest food prices in the world. American consumers benefit from a generous supply of edible and appealing products, both fresh and processed. The food supply is safe, and as the NAS noted in an earlier study on the relationship of diet and health, children benefit, as we all do, from the nutritional content of fruits and vegetables.

The study is valuable in that it evaluates where we can still show room for improvement. It makes several important recommendations, many of which are addressed in our legislation, among other things. The Lehman-Bliley-Rowland bill, H.R. 1627, entitled the "Food Quality Protection Act," mandates that EPA consider the exposure of sensitive population subgroups, such as infants and children, when setting pesticide tolerances for foods. The bill calls for better data, an improved assessment of what children eat, encouragement of alternative techniques such as integrated pest management, and a more efficient system for removing unsafe pesticides from the market.

While my esteemed colleagues, Senator Kennedy and Congressman Waxman, offer an alternative approach to food safety reform, I believe our bill is the best model for a variety of reasons. While

both of our bills resolve the Delaney Paradox by calling for a negligible risk standard, the Lehman-Bliley-Rowland bill allows for the flexibility needed to respond to important scientific developments, such as this study reflects.

If we again make the mistake of locking in current science, as we did with the Delaney Clause many years ago and as the Kennedy-Waxman bill calls for, we repeat the mistakes of the past which have led to an outdated, unresponsive system that can only be improved through legislative action. The NAS report confirms the complexity of risk assessment. I do not believe that Congress is the right body to make this scientific, unbiased analysis.

Our legislation is also the more comprehensive approach in that it addresses the need for an expedited review process under FIFRA to take unsafe chemicals off the market. Without also improving registration, we really have no food safety reform at all.

Finally, the interests of safety are not exclusive of the benefits, such as abundance and affordability, which are derived from pesticide use. The two must be adequately balanced to ensure the highest quality, lowest cost, most dependable food supply possible, which promotes the health and well-being of the American public. Let us not forget that anything in large doses, including aspirin, can pose a danger, but if safely used can work effectively.

I share the belief that our food supply needs to be as safe as possible, and it is important to note that the fundamental standard in our bill directs EPA to ensure that public health is protected. Does that mean that without a definition written into law we are not taking adequate precautions? Absolutely not. Rather, we are providing scientists the flexibility to implement our standards of protecting public health using the most up-to-date scientific methods and data available.

The study does not say our current risk assessments are wrong; it says we could be doing them better. Let us build on our model, which has the broad, bipartisan support of over 100 members in the House of Representatives, and leave EPA with the discretion to adapt the future developments in science, as we are encouraging them to do today.

Again, Mr. Chairman, I appreciate this opportunity. I really look forward to working with this committee as we move forward in this area. I think it is important that we develop policies here and strategies based on scientific evidence and not on the hysteria of the moment. I think everyone should know our food supply is safe, we can make it safer, and we will.

[The prepared statements of Congressmen Rowland and Bliley follow:]

PREPARED STATEMENT OF HON. J. ROY ROWLAND, A REPRESENTATIVE IN CONGRESS FROM THE EIGHTH CONGRESSIONAL DISTRICT, STATE OF GEORGIA

Thank you Mr. Chairman. I appreciate the opportunity to testify before the Senate Agriculture Committee on such an important issue.

The U.S. food supply is the safest, most wholesome and abundant food supply in the world. Today's foods are safe from pathogens, diseases, and parasites and are more nutritious than ever. Pesticides and fertilizers are crucial to the production of our high quality food supply.

The news reports surrounding the release of the National Academy of Sciences (NAS) study have been a little disconcerting. The Washington Post headline was

"Pesticide risk may be higher in children." Newsweek's article stated "Better watch those fresh fruits."

As a family physician for 28 years, I too have concerns about any study which raises questions about the health of our children, but we must be careful not to jump to any conclusions about what the NAS study actually determined.

Government officials need good data to develop policy. The public also wants to know the facts. Unfortunately, most of the available information is in the form of "sound bites." Complicated issues, such as the findings from this study, which do not make any final determination about the risks of pesticide use, do not bode well in this environment. The reaction to the study shows that the media only has time for "facts" out of context and has not taken the time to look at what the study actually says.

The NAS study has found that, "The current regulatory system does not specifically consider infants and children." I take this to mean that good data is lacking. In addition, the study found that "Risk assessment methods that enhance the ability to estimate the magnitude of the effects must be considered." This does not mean that children must stop eating fruits and vegetables but it does mean that we need to collect more data and establish a good risk assessment methodology in order to determine whether children are, in fact, at risk of overexposure to pesticides.

At yesterday's press conference at the National Academy of Sciences, Dr. Philip Landrigan was asked how many pesticide chemicals will be lost if the NAS recommendation were followed. Dr. Landrigan stated that the wholesale banning of pesticides as a result of the study is inappropriate, and that what is required is better management of pesticide risks. That is exactly the intention of H.R. 1627.

H.R. 1627 provides the EPA with the tools that it now lacks to better regulate the use of pesticides, and the presence of pesticide residues in foods. Our bill would allow EPA to more quickly remove unreasonably risky pesticides from the marketplace. Also, the bill eliminates the inconsistencies and irrationalities of current law by establishing a single uniform risk standard for pesticide residues in all foods.

Mr. Chairman, I want to emphasize that we must provide our Government's scientists and regulators the flexibility to do their jobs. In crafting pesticide legislation, we should not succumb to the temptation to prescribe in inordinate detail the way EPA should do its job.

Thank you, Mr. Chairman. I look forward to working with your committee on this important issue.

PREPARED STATEMENT OF HON. THOMAS BLILEY, JR., A REPRESENTATIVE IN CONGRESS FROM THE THIRD CONGRESSIONAL DISTRICT, STATE OF VIRGINIA

Mr. Chairman, I appreciate this opportunity to testify regarding our Nation's regulation of pesticides, particularly pesticides used in production of our food supply. I am pleased to cosponsor with Mr. Lehman and Mr. Rowland H.R. 1627, as I cosponsored similar legislation in the last Congress with Mr. Bruce. We have been working for quite awhile now on comprehensive reform of our pesticide regulatory system. It seems that the importance of accomplishing this type of reform steadily builds both in terms of ensuring public health and permitting the use of safe pesticides.

In July 1992, the Ninth Circuit Court of Appeals struck down the Environmental Protection Agency's de minimis policy with respect to pesticide residues in processed foods. This de minimis policy was based on a previous report by the National Research Council. In rejecting the de minimis policy, the Court directed EPA to implement the literal meaning of the Delaney Clause in section 409 of the Federal Food, Drug, and Cosmetic Act. The de minimis policy was a reasonable effort to make sense of a provision of law, the Delaney Clause, that has proven inimical to the public well-being.

In implementing the decision of the Ninth Circuit Court of Appeals the EPA must exercise all appropriate discretion to assure that we do not unnecessarily lose safe and effective pesticides necessary to an economical food supply. However, the Delaney Clause and now the National Research Council's newest report on the risk of pesticides to infants and children means that we must act during this Congress to pass pesticide reform legislation. In moving forward with comprehensive pesticide reform legislation we must avoid the temptation of legislating by the crisis of the day and instead bear in mind the context of the problem we are addressing.

The first priority of any reform legislation must be to reorient EPA's pesticide regulatory focus away from the Delaney Clause and the enforcement of the unrealistic zero-risk prohibition against cancer risk. We need legislation that adopts a modern standard of risk. This standard must provide the agency the flexibility to

balance all relevant risks and encourage the introduction of safer pesticides. H.R. 1627 is designed to accomplish these things.

Mr. Chairman, that collective groan you heard from all across America when the National Research Council released the report was the disappointment of children everywhere that they will have to continue to eat their peas and brussel sprouts. It is to the credit of the officials representing the Council that they so clearly conveyed the message that children should continue to eat fruits and vegetables. The day this Congress passes H.R. 1627 is the day that parents can stop worrying about the risks of pesticide residues in the food supply. Our bill would firmly establish in law a negligible-risk standard intended to protect all humans—from infancy to adulthood. In addition, unlike any other bill introduced in this Congress, our bill provides EPA the authority to restrict or eliminate the use of unsafe pesticides.

Mr. Chairman, we are dedicated to improving our pesticide regulatory system so that the American food supply will become even safer and remain the world standard. In this scientific age when the most infinitesimal amount of a chemical can be detected, we must bear in mind that balance must be the guiding principle. Public health is best served by the regulation of pesticide residues in a fashion that provides an adequate, economical and wholesome food supply.

The CHAIRMAN. Thank you very much. I appreciate your coming, especially with the perspective you bring to this issue not only from your own background but certainly from the area that you represent, an area that outproduces an awful lot of countries in the world.

I thank you very much.

Mr. LEHMAN. That is true. Thank you.

The CHAIRMAN. I noted earlier that the ranking member, Senator Lugar, was delayed at another meeting. He passed up his chance to give an opening statement earlier out of deference to our three colleagues, and I would yield to Senator Lugar now.

STATEMENT OF HON. RICHARD G. LUGAR, A U.S. SENATOR FROM INDIANA

Senator LUGAR. Thank you, Mr. Chairman.

I thank you for convening this hearing to discuss the findings of the National Academy of Sciences report.

Pesticide residues on infant foods, and adult foods that infants eat, are almost always well below the highest permissible levels set by the Environmental Protection Agency. This was the conclusion of a recent FDA report based on the agency's own monitoring of these foods over the past 7 years. While such news is promising and suggests that in general our Nation's food supply and our Nation's food safety net works well, it does not mean there are no holes in the net.

The Academy has done an impressive job in its evaluation of methods used to estimate health risks to infants and children from dietary exposure. In doing so, the Academy has found some holes in the net that are in need of mending. Specifically, the Academy has called for increased collection of data on the consumption of food by infants and children, along with more information on pesticide residues found on food. Together, these changes will enable our Federal agencies to better characterize risks.

Recommendations for the establishment of toxicity testing procedures that specifically evaluate the vulnerability of infants and children make good sense and appear well founded. It is important to note, however, that these recommendations do not signify the failure of our Federal agencies to protect children but rather are part of a natural evolution of science as our knowledge base ex-

pands. They represent the next logical step in our regulatory scheme based on current information.

I was particularly impressed with the Academy's balanced view on the establishment of pesticide tolerances. While calling for a greater emphasis on health considerations, the Academy recognized the need for the continued consideration of the requirements of agricultural production.

The Academy recommends that certain changes be made in current regulatory practice, and members of this committee will have the opportunity to oversee this process. The Federal Insecticide, Fungicide, and Rodenticide Act is due to be reauthorized during this Congress. In doing so, I am confident that this committee will work closely with the Federal agencies involved to address the issues raised by the Academy to ensure the protection of our Nation's most valuable resource, our children.

Thank you very much, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Lugar.

Senator Feingold, did you have an opening statement?

STATEMENT OF HON. RUSS FEINGOLD, A U.S. SENATOR FROM WISCONSIN

Senator FEINGOLD. Thank you, Mr. Chairman.

I commend the chairman not only for holding this hearing to discuss the results of the study but also for initiating over 5 years ago the examination of the safety of our food supply for infants and children.

I would like to learn more about how we can improve the safety of our food supply for all segments of the population, but most importantly for our children. The questions raised by this analysis challenge fundamental principles surrounding Government regulation of our food supply.

Of course, I am interested in learning about this issue not only from the perspective as a policy maker but also from the perspective of being a parent of young children. I care very much about the types of foods my children eat as well as the safety of those foods, and I know millions of American parents share those concerns.

We are very lucky as parents in the United States in that our country has probably the most affordable food supplies in the world and also we are fortunate enough to have the safest food supply in the world. That is a unique balance of what some might call competing goals. That is due to our careful monitoring and regulation of our food supply from the farm to the processor to the grocery store and beyond. Credit has to be given to agricultural producers in this country who are increasingly proving that sound stewardship of the land and a high-quality, affordable, and safe food supply can coexist.

However, as we make advances in science and technology and our understanding of food safety issues broaden, I believe it is our responsibility to strive to actually enhance the safety of our food supply.

That is why I am pleased that the question of the impact of pesticides on children has been raised and that the answers have been

based on sound scientific data and reasoned analysis rather than just assumption and speculation.

I think it is also worthy to note that one of the major items we are taking up in the Senate this week has to do with the GATT talks. One of the concerns I have heard in Wisconsin has to do with whether or not a GATT agreement would allow imports of food products into this country with a higher pesticide level. It is certainly relevant as we look at GATT to also consider whether or not those conditions exist in our own country and how the two working together may have an effect on the pesticide level in our foods.

I would also like to mention just very briefly, Mr. Chairman, that this whole topic, as you know better than most, brings up, inevitably, the subject of low-input sustainable agriculture and some of the alternatives in that area that have such tremendous potential to reduce pesticide use. I have had the good fortune to work with the Wisconsin Rural Development Center and others who believe that this subject is tied in with the question of the existence of family farms and our ability to promote sustainable agriculture as a way to not only keep the farms but also address the issue before us today.

The policy issues are not simple, and we are well served to have such well-respected scientific experts before us today. I thank the chairman for making this possible.

The CHAIRMAN. Thank you very much, Senator Feingold.

Senator Cochran, did you have a statement before we start with the panel?

STATEMENT OF HON. THAD COCHRAN, A U.S. SENATOR FROM MISSISSIPPI

Senator COCHRAN. Yes sir, Mr. Chairman.

I just wanted to make a point, and I appreciate your recognizing me, that this committee is united in our commitment to help ensure that the citizens of the United States have access to safe and wholesome food. This applies especially to the children in our Nation.

As we approach decisions and actions that we are contemplating, I think it is also important for everybody to know that we realize those decisions and actions must be based upon facts and reliable scientific research. I think working together we are going to help see that legislation, regulations all are designed to help achieve this important goal for the people of our country.

The CHAIRMAN. Thank you very much.

I am glad to have Senator Daschle, who has had a great deal of interest in this whole area, with us.

At this point, I would like to include the statement of Congressman Mike Synar of Oklahoma for the record.

[The prepared statement of Mr. Synar follows:]

PREPARED STATEMENT OF HON. MIKE SYNAR, A REPRESENTATIVE IN CONGRESS FROM THE SECOND CONGRESSIONAL DISTRICT, STATE OF OKLAHOMA

Here we go again. Every few years we find another critical review of EPA's pesticide program, this time by the National Academy of Sciences. Every few years, sometimes every few months, we hear another call for food safety reform. We see EPA ignore deadlines of the law, directives by the courts, and demands by consum-

ers. Now we discover that EPA's standards aren't protective of children and infants—but guess what, EPA's standards aren't protective of anyone, except maybe the pesticide companies.

I hope this year, this Congress, and this administration will get to the important tasks at hand. We know FIFRA is a failure. Just yesterday, Chairman Leahy and I released a GAO report which revealed that EPA will miss its deadlines to complete reregistration as mandated in the 1988 amendments. These deadlines in turn were an attempt to complete the tasks set out in the 1972 amendments. But the report's title says it all: "Pesticide Reregistration May Not Be Completed Until 2006." After 20 years of implementation, EPA has completed the reregistration of only 31 of almost 20,000 pesticide products. **At this rate—31 out of 20,000 since 1972—reregistration will take EPA until the year 15,520 A.D. to complete.** Progress in this program is better measured in units of geologic time.

Also this week, we have released the published record from a hearing held last summer by the House Government Operations Subcommittee on Environment, Energy, and Natural Resources, which I have the honor of chairing. The record from that hearing revealed that even with the flawed food consumption data currently in use, 34 pesticides had possible residues which exceeded the safety standard by more than 1,000 percent for infants aged 1–6. [1]

The NAS report recommends that we should add another tenfold safety factor to protect children from the risk of many pesticides. If such a new standard was in place, these 34 pesticides would then exceed the safety standard by over 10,000 percent—**100 times over the "safe" level.** If other recommendations of the report are followed and additional safety factors are indeed found necessary to protect children, you can see that EPA's longstanding neglect of these risks is simply intolerable.

The subcommittee's hearing also revealed that 67 pesticides in our food cause cancer, and that 98 contaminate our groundwater.

All the while consumers raise questions about the possible risks of pesticides in their food and water.

All the while farmers and ranchers ask how we've gotten to this point, where food scares can dry up the market for a product overnight, even though Federal agencies know of the potential controversies years or decades in advance.

All the while, EPA's pesticide program budget is almost 1,100 workyears, of which only five staff positions are devoted to integrated pest management, and only 20 workyears are devoted to supporting registration issues for fruits and vegetables and other specialty crops.

All the while, food companies tell the public not to worry since a "risk/benefit" calculation proves all is well. What they don't mention is that it is often "your risk/their benefit" when consumers buy food for their families.

All the while, Congress continues its gridlock about how to proceed. I hope we can begin to do our part, and bring these long-standing issues to a reasonable close. I look forward to working with Chairman Leahy and other Members in the Senate and House on putting this program on a path toward completion. In that spirit, I would like to offer some initial suggestions:

- Finish reregistration by the year 2000. Supporting this task will require additional fees imposed on the pesticide industry.
- Accelerate the process used to review potential problem pesticides. The current process takes 7–15 years to resolve safety issues, which hurts consumers, producers, and even pesticide manufacturers as uncertainty lingers.
- Protect special populations, children included, with standards which reflect modern science, such as those contained in the NAS report.
- Arrange incentives for accelerated innovation of safer pest control practices, chemical or nonchemical. This may require priority reviews or conditional registrations for lower risk products.
- Devote 10 percent of the research and education budget of USDA to an EPA-directed effort to help farmers and ranchers produce our food with minimal risk to public health and the environment. In the mid-1980's, OMB ruled using EPA funds to research pest control alternatives was inappropriate; that action left a vacuum between the agendas of the regulators and the researchers. This lack of interagency coordination must be addressed to the benefit of farmers, ranchers, and consumers alike.

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[1] "Thirty Years After *Silent Spring*: Status of EPA's Review of Older Pesticides," Hearing by the House Government Operations Subcommittee on Environment, Energy and Natural Resources; July 23, 1992.

I hope these thoughts are useful to the committee in reviewing the results of the NAS study. I look forward to working with you on this important issue and thank you again for the opportunity to present these comments.

The CHAIRMAN. I would ask if the panel would come forward. We have three distinguished members of the National Academy of Sciences panel. Representing the Academy is Kenneth Shine, the President of the Institute of Medicine. Representing the committee is its Chairman, Dr. Philip Landrigan, Professor and Chairman of the Department of Community Medicine and Director of the Division of Environmental and Occupational Medicine at the Mount Sinai School of Medicine.

Joining Dr. Landrigan are Dr. Donald Mattison, vice chair of the panel and dean of the Graduate School of Public Health of the University of Pittsburgh and Dr. Richard Jackson, chief of the Office of Communicable Diseases, the California State Department of Health Services.

I not only want to thank you, to begin with, for spending the time here, but for the countless hours—in fact, you probably don't want to be reminded of the number of hours you and your colleagues put into this report.

I should also note for the public, for anybody who may be watching this on C–SPAN, the committee members served on a voluntary basis. This report would not have been possible without their commitment to protecting America's children, so I compliment you for that.

Dr. Shine, why don't you go ahead, please.

STATEMENT OF KENNETH SHINE, M.D., PRESIDENT, INSTITUTE OF MEDICINE, NATIONAL ACADEMY OF SCIENCES

Dr. SHINE. Mr. Chairman and members of the committee, good morning. I am Dr. Kenneth Shine. I serve as president of the Institute of Medicine of the National Academy of Sciences.

We appreciate the opportunity to review with you our report on "Pesticides in the Diets of Infants and Children," which was prepared by a blue-ribbon panel operating under the joint auspices of the Board on Environmental Studies and Toxicology and the Board on Agriculture of the National Research Council.

This report, as you note, was prepared at the request of Senator Leahy and the Senate Appropriations Committee, which directed that the Environmental Protection Agency contract with the National Research Council, the research and operating arm of the National Academy of Sciences, Engineering, and the Institute of Medicine to undertake the study.

Clearly, we knew from the outset that the question of whether there are pesticide residues in the U.S. food supply is a highly sensitive one affecting many communities and interests and potentially creating substantial economic impacts on U.S. agriculture.

Thus, operating under the standing policies of the National Research Council and as noted by Congressman Waxman, we went to great lengths to ensure that the special panel organized to address the problem would be both carefully balanced and broadly representative of the full range of interests, and the membership of the panel is noted in the report.

We believe this report is a fair and objective treatment of a highly complex problem, and I want to emphasize to you that the study panel was unanimous in its recommendations.

As you are aware and as Senator Craig has noted, the study required more than 3 years to complete. This length of time was unusually long, even by NRC standards, and it reflected both the overall complexity of the problem and the fact that there were and are serious problems with the data that was available to the committee for its analysis.

Despite these difficulties and delays, the committee ultimately made a number of important intellectual breakthroughs regarding how to approach risk assessment in the use of pesticides. We believe that its recommendations will be helpful to the Congress and to the executive branch agencies responsible for environmental health, food safety, and agriculture.

I would like to reiterate the point that you, Mr. Chairman, made, that this group served entirely as volunteers, that they put in countless thousands of hours of pro bono time to assemble this report, that it is the result of a deliberative process in which they carefully examined the scientific basis of their recommendations, and the result of their work, the report, was then subject to additional peer review by anonymous peer reviewers so that the product that we have produced is the result of both their efforts and the critique of other knowledgeable scientists in the field.

The committee was chaired by Dr. Philip Landrigan, who, as you noted, is a pediatrician and a Chair of the Department of Community Medicine of Mount Sinai School of Medicine in New York, and he will give you a summary of the committee's recommendations.

The CHAIRMAN. Thank you very much, Dr. Shine.

Dr. Landrigan.

STATEMENT OF PHILIP J. LANDRIGAN, M.D., DEPARTMENT OF COMMUNITY MEDICINE, THE MOUNT SINAI SCHOOL OF MEDICINE, NEW YORK, NEW YORK, AND CHAIRMAN, COMMITTEE ON THE SCIENTIFIC AND REGULATORY ISSUES SURROUNDING PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL ACADEMY OF SCIENCES

Dr. LANDRIGAN. Thank you, Mr. Chairman and members of the committee.

I am very pleased to be here before you this morning to report on the subject of "Pesticides in the Diets of Infants and Children." I would like to begin by thanking you for having charged the National Academy of Sciences 5 years ago to convene our committee to enable us to embark upon this work.

This was work that I and the members of the committee took extremely seriously. We considered it to be of great importance and we were extraordinarily pleased to have had the privilege of serving with each other, with the National Academy of Sciences, and under your direction in this matter.

The major conclusion of the study is that the Federal Government's decisionmaking process for regulating pesticides in foods does not pay sufficient attention to the protection of human health,

and in particular, that the current regulatory system does not pay enough attention to protecting the health of infants and children.

A fundamental problem in this regulatory system is that it takes a one-size-fits-all approach. That is to say, it simply does not consider the differences that are obvious between adults and children.

Children are different from adults in a number of respects, but the two areas that we highlighted in this analysis were, first of all, differences in exposure, and secondly, differences in biological susceptibility.

The differences in exposure to pesticides derive from the fact that children's diets are very different from those of adults. They eat fewer foods than we do as adults and at the same time they eat more food, more calories per pound of body weight than do adults. This combination of factors means that their risk of exposure to pesticides can be substantially greater than that of adults if the circumstance arises in which one of those foods that is concentrated in children's diets happens to be contaminated with pesticides.

The difference in biological susceptibility reflects the obvious fact that children are growing and developing. During the early years of childhood, the basic structure, the basic anatomy, the basic physiology of many organ systems, such as the nervous system, the immune system, the reproductive organs are still being established. The formation of those organ systems is not complete at birth but continues throughout the early years of life, and in the case of the nervous system probably continues up until adolescence. Because this growth and development is proceeding through those early years, children are vulnerable to pesticides.

In some instances, of course, there are counter-examples. There are some pesticides to which children are actually less sensitive than adults because they handle them a bit better, but the general rule is that children are more sensitive.

I want to make it plain, and you have already touched on it, but I think it is important I reemphasize that the goal of this analysis and the goal of our report is not to create some kind of food panic. Rather, our goal was to make the very good food supply that we already have in the United States even better.

I had the opportunity in my life when I served with the U.S. Public Health Service to work as a pediatrician in Third World countries in Central America and in West Africa. I have seen first hand, I have held babies that were suffering from malnutrition, and I can assure you that the difference in nutrition between our babies in this country and those poor children overseas is vast. I can attest directly to the high quality of the food supply in this country and to its beneficial effects upon our children.

At the same time, I feel impelled on the basis of the analysis that we have conducted to urge the regulatory agencies and those of you who have responsibility for their oversight to do even better than they are doing today. There is still room for improvement.

In particular, we recommend that the regulatory agencies adopt a new method of risk assessment that will enable them to more accurately gauge the population at risk and then more effectively to protect that population.

In the course of making this recommendation to the agencies, we most certainly do not want to in any way dissuade parents from

continuing to feed adequate amounts of fruits and vegetables to their children. One of the great gains in pediatrics and in nutrition science over the past 10 or 15 years has been the recognition of the important health benefits that are conveyed by fruits and vegetables.

It is very important that the positive trends that have been achieved over the past decade in increasing fruit and vegetable consumption be continued. The last thing we want to do through this report is to somehow encourage parents to start throwing fruits and vegetables away and going to other foods.

A central aspect of our analysis concerned the subject of tolerances. The term tolerance, of course, is the technical term given to the permissible limits of pesticide in food, the limits that are set by the Food and Drug Administration and by the EPA.

It was the firm conclusion of our committee that tolerances must be health based. Under current legislation, as you well know, the setting of tolerances involves a balancing process. Issues of agricultural practice are balanced against issues of health and safety.

Unfortunately, we learned in the course of our analysis that there exist examples, well-documented examples involving pesticides, herbicides, and fungicides where agricultural considerations have taken precedence over health considerations in the setting of standards.

We strongly recommend to the regulatory agencies that this situation be reversed and that procedures be put in place that clearly give precedence to health considerations, particularly the protection of the health of infants and children in the setting of tolerances.

We made a number of technical recommendations to the agencies. I won't go into those in great detail in my presentation here, because I want to keep it brief, but let me enumerate them, and I would be prepared to take questions.

First of all, we made a very detailed technical recommendation as to how the agencies ought to conduct risk assessment. We want the agencies to get away from the present approach to risk assessment in which the whole American population, all 250 million of us, are considered as one average human being in the present scheme for the weighing of risks.

Variations between the sexes, among the races, among the age groups, among the many ethnic groups that comprise the mosaic of our country are all overlooked in the present risk assessment scheme, and that is no longer necessary. It is possible with current computer technology to actually look at the whole range, at the whole spectrum of exposures that exists across our population and do risk assessment accordingly.

We have provided detailed recommendations in this regard to the agencies, and to make life relatively easy for the agencies, we have also provided computer software to them so that they may take our guidance and do their own analyses using the numbers that are available to them.

We urge on a technical ground that there be much more effective testing of the toxicity of pesticides than is currently the case. We identified numerous gaps in toxicity testing, especially in regard to toxicity testing among the young.

We finally recommend that surveys of exposure to pesticides in the diet, market basket surveys, so called, be improved in their quality and that they focus better than they do today on the diets of children and on the exposures of children.

In summary, Mr. Chairman, our committee believes that children deserve special consideration when it comes to pesticide regulation. We believe that by taking the particular steps that we have outlined in our report, the agencies of the Federal Government could go a long way towards ensuring that the health of our children is not compromised and that America's future is conserved.

Again, I thank you very much for having invited us here today, and my colleagues and I will be pleased to take any questions.

[The prepared statement of Dr. Landrigan follows:]

PREPARED STATEMENT OF DR. PHILIP J. LANDRIGAN, DEPARTMENT OF COMMUNITY MEDICINE, MOUNT SINAI SCHOOL OF MEDICINE, NEW YORK, NY, AND CHAIRMAN, COMMITTEE ON THE SCIENTIFIC AND REGULATORY ISSUES SURROUNDING PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL ACADEMY OF SCIENCES

Mr. Chairman: I am Philip Landrigan, chairman of the National Research Council's Committee on Pesticides in the Diets of Infants and Children. I am accompanied by the vice chairman, Donald Mattison, of the Graduate School of Public Health, University of Pittsburgh, and by Richard Jackson of the California State Department of Health Services, who is a member of the committee. We are pleased to be here to discuss our report, "Pesticides in the Diets of Infants and Children." As a pediatrician, I believe that this is a subject of great significance. And speaking on behalf of my distinguished colleagues on the committee, I want to convey to you the importance we placed on the charge we were given to determine the extent to which Government scientific and regulatory programs are protecting the Nation's children from pesticides in their foods. I also want to thank the committee that prepared the report. These 14 people volunteered an enormous amount of time in what has proved to be one of the National Research Council's most ambitious studies.

The major conclusion of this study is that the Federal Government's decisionmaking process for pesticides does not pay sufficient attention to the protection of human health, especially the health of infants and children. The Government's current regulatory program takes a one-size-fits-all approach, even though children differ greatly from adults not only in size but also in metabolism and in what they eat.

A fundamental tenet of pediatric medicine is that children are not just little adults. They are in many respects truly different. Unfortunately, current pesticide regulation does not adequately reflect that understanding. Today's regulatory system does not specifically consider variations in pesticide exposure between adults and children. Neither does it consider the ways in which children's bodies may react differently to foreign substances. As a result, concern has arisen that at least some American children may be ingesting unsafe amounts of pesticides in their diets.

Our report recommends that the Federal Government change some of its scientific and regulatory procedures for limiting pesticide residues in children's diets. It also recommends that regulators adopt a new method of risk assessment to more accurately gauge the population at risk. And it urges that toxicity testing of pesticides be more comprehensive.

The goal of our report is to make the very good food supply of the United States even better. We have directed our report primarily to those who make decisions about pesticide use and those who regulate pesticides. We are not saying that parents should rush out and radically change their children's diets to avoid certain foods. We do not say in our report that some particular food is terribly dangerous for children and needs immediately to be discarded. Parents should continue to emphasize fruits and vegetables in their children's diets. What we are saying is that basic changes are needed in the current regulatory system to ensure that foods eaten by infants and children are safe.

Tolerances constitute the only mechanism available to the Government for regulating pesticide residues in foods. Thus we recommend that the Government have as its clear goal the setting of tolerances that more fully protect human health, including the health of infants and children.

Children tend to eat fewer kinds of foods compared with adults and so they consume more of certain foods per unit of body weight. In addition, they drink more water, both alone and mixed with other foods. But the current regulatory system does not consider these differences between children and adults. Neither does it do a good job of considering the differences in diets between children of different ages, ethnic backgrounds, and regions of the country.

We suggest a new approach that would look at the diets of infants and children separately from those of adults. Current risk assessments use a single number to represent the average exposure of the entire population to pesticides. But this method overlooks children on both ends of the spectrum—those who receive above-average exposures as well as those who receive below-average exposures. We recommend, instead, a statistical technique that combines data on the kinds and quantities of foods eaten by children with data on the pesticide residues on those foods. This kind of combined analysis would help regulators determine what the exposure level is for children in a variety of circumstances, rather than looking only at average exposure.

Using this approach could give a much better picture of how many children might receive exposures above the level thought to be safe. This information could be used for setting tolerances, which are the amounts of pesticides legally allowed on or in foods when they leave the farm. In our report, we present a detailed road map for this new approach to risk assessment.

We note that a major obstacle to the use of this new approach is a lack of data in certain areas. Clearly, more accurate risk assessments will not be forthcoming without better information on food consumption patterns, pesticide residues, and toxicity. Our report includes a slate of specific recommendations on ways to generate these data.

We believe that the Federal Government should revamp significant aspects of its approach to pesticide regulation. Food consumption surveys need to monitor narrower age groups to determine how children's diets differ from those of adults. For example, a 1-year-old child does not necessarily eat the same types of foods as a 4-year-old. Yet current surveys tend to group children in broad categories, such as 1–6-year-olds.

We also believe that measurements of pesticide residues should be standardized across the Nation and computerized. These measurements need to reflect children's diets, the different rates and methods of pesticide application, and the effects of food processing on pesticide concentrations. Furthermore, regulators must take into account children's exposure to pesticides from nondietary sources. Water, air, soil, lawns, and indoor surfaces all must be considered as potential sources of exposure. Also, regulators must recognize that children may be exposed to multiple pesticides with common toxic effects.

Toxicity testing procedures should be developed that specifically evaluate the vulnerability of children. Of particular importance are tests for toxicity to the developing immune, nervous, and reproductive systems.

We encourage EPA to consider expanding the use of uncertainty factors that are already used in extrapolating from animal tests to determine effects in humans.

Currently, if animal tests show no adverse effects at a certain exposure level, then the level that is thought to be safe is determined by dividing that no-effect level by 100. This accounts for differences between humans and animals as well as variation among humans. EPA then divides this number again by 10 if studies have shown effects on the developing fetus. We recommend expanded use of this additional uncertainty factor. Specifically, we believe that EPA should consider using an additional factor of up to 10 when there is evidence of postnatal toxicity or when data from toxicity testing relative to children are lacking.

And we recommend that estimates of cancer risk from pesticides take into account changes in exposure and susceptibility that occur throughout a person's life. Children who are exposed to a carcinogen early in life have many more years of life ahead of them than do adults to manifest a cancer that may be triggered by that exposure.

In summary, our committee believes that children deserve special consideration when it comes to pesticide regulation. By taking the special steps we have outlined in our report, the Federal Government could go a long way toward ensuring that their health is not compromised and that America's future is conserved.

Mr. Chairman, my colleagues and I will be pleased to answer any questions.

The CHAIRMAN. Thank you very much, Dr. Landrigan.

Dr. Mattison, were you going to add to this, either you or Dr. Jackson at this point, or are you prepared to just answer the questions?

Dr. MATTISON. I have just a couple of brief comments I would like to make if I could, Mr. Chairman.

The CHAIRMAN. Please do.

STATEMENT OF DONALD R. MATTISON, M.D., GRADUATE SCHOOL OF PUBLIC HEALTH, PITTSBURGH, PENNSYLVANIA, AND VICE CHAIRMAN, COMMITTEE ON THE SCIENTIFIC AND REGULATORY ISSUES SURROUNDING PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL ACADEMY OF SCIENCES

Dr. MATTISON. Mr. Chairman, distinguished members of the committee, the charge that this National Academy of Sciences committee was given was to critically examine the methods by which risks to infants and children are characterized. We found, as has been indicated, that the current regulatory practice needs to give greater consideration to infants and children.

We have identified, as has been indicated by Senator Lugar, that this is an evolving area of science and that there are a series of areas in which there are substantially increased available data to improve the risk assessment methodology. These include food consumption data, pesticide residues on the foods, test development, and risk assessment methods, and we lay out in the report a way in which each of those areas can be addressed.

We agree as a committee that the food supply is safe but that we need to begin to work with our continued knowledge base to enhance the safety for infants and children.

Thank you very much.

The CHAIRMAN. Thank you very much, Dr. Mattison.

Dr. Jackson.

STATEMENT OF RICHARD J. JACKSON, CHIEF, COMMUNICABLE DISEASES, CALIFORNIA STATE DEPARTMENT OF HEALTH SERVICES, BERKELEY, CALIFORNIA, AND COMMITTEE MEMBER, COMMITTEE ON THE SCIENTIFIC AND REGULATORY ISSUES SURROUNDING PESTICIDES IN THE DIETS OF INFANTS AND CHILDREN, NATIONAL ACADEMY OF SCIENCES

Dr. JACKSON. I think my colleagues have made a fine introduction, and I will wait until the questions.

Thank you, Senator.

The CHAIRMAN. Thank you very much.

I do want to thank Dr. Shine, Dr. Landrigan, Dr. Mattison, and Dr. Jackson for their work.

Let me see if I can give a quick layman's summary of what you have done. Your report says that children are different from adults in their sensitivity to many of the chemicals in use today, that they are exposed to greater amounts of pesticides due to their smaller size and sometimes because of their less-varied diets or perhaps because of their more specific diets, and the combination of greater sensitivity and greater exposure means that a significant portion of children may be at risk from pesticides in foods.

With that layman's summary, and I realize a superficial one, Dr. Landrigan, let me ask you a couple of questions. I understand first that we don't have as much information on children's eating habits or as detailed information as we might like, but there is still a lot of information about what children eat. They eat a lot more of some foods as a percentage of their body weight than adults do.

You point out in your report that nonnursing infants consume, I think it was 63 times the national average of orange juice and about 15 times for fresh pears. Obviously, that is a good example of where——

Dr. LANDRIGAN. Some do, Mr. Chairman.

The CHAIRMAN. I beg your pardon?

Dr. LANDRIGAN. Some do. There is obviously a range of exposure.

The CHAIRMAN. Sure, but those are just some indications of some areas where certain specific foods are consumed at a much higher rate by infants or very young children than they are by adults.

Are some children exposed to greater amounts of pesticides based on their unique consumption habits?

Dr. LANDRIGAN. Yes, Mr. Chairman, that was a very comprehensive summary.

And one of the points that we make and make repeatedly in the report is that the current procedures for risk assessments that are used by the agencies that focus only on the average human being would miss that range of exposures. Current procedures would miss the child who consumes 63 times or 28 times the average exposure because they look only at the average.

We think that with the new procedures that we have outlined here, the agencies will really be able to take a look at those children who are at greatest risk and find better ways to protect them.

The CHAIRMAN. You can't use just an overall average if you are going to be specific for children?

Dr. LANDRIGAN. No, it just doesn't work. That would be like saying that the average speed on the interstate was 43 miles an hour. We know full well that some people go at 95 and some creep along at 20.

The CHAIRMAN. So does that mean that the present system is not adequately protecting a significant number of children?

Dr. LANDRIGAN. To put it more positively, the current system needs to be improved, yes sir.

The CHAIRMAN. Now you raise the question of children's sensitivity to chemical pesticides. I realize it is very complicated, but in layman's terms, can we assume that children are different from adults in their sensitivity to chemical pesticides?

Dr. LANDRIGAN. Yes sir, absolutely.

The CHAIRMAN. Are they more sensitive to some, less to others?

Dr. LANDRIGAN. More sensitive to most, less sensitive to some.

The CHAIRMAN. That is interesting. But there are actually some that they are less sensitive to than adults are?

Dr. LANDRIGAN. Yes. There are some well-documented examples, you might refer to them as counter examples, counter-intuitive examples, that we mention in our report, where children's livers and kidneys are actually more efficient than those of adults at breaking them down and excreting certain chemicals.

The CHAIRMAN. But at the same time, they are also developing their immune systems and major elements of their nervous systems. I mean, they don't come at birth with a fully-developed immune system, fully-developed nervous system. That is still under development in children, is that correct?

Dr. LANDRIGAN. That is correct, all through early childhood.

The CHAIRMAN. And are those areas where they can be specifically or especially affected by chemicals and pesticides?

Dr. LANDRIGAN. Yes, Mr. Chairman. One of the concerns we have here, I should say that it is somewhat speculative but by no means entirely so, is the notion that if a certain number of cells in the developing nervous system are damaged early on, let us say in the second, third, fourth year of life, the child might apparently function quite well through childhood and through early adulthood.

But the concern arises that perhaps four or five decades later, as we all begin to age and we all lose a certain number of neurons each day of our lives as we get older, that if a child lost a number of neurons, nerve cells, early in life as the result of some toxic exposure, then the situation could theoretically arise that when today's child is 60 years old, sometime in the middle of the next century, that child will no longer have enough neurons to sustain coherent thought and would appear clinically as Alzheimer's disease or dementia or Parkinson's disease.

This notion of delayed damage to the nervous system is a topic that we mention in this report and that was discussed in much more detail in another report from the National Academy that I chaired last year on environmental neurotoxicology.

The CHAIRMAN. So does EPA need new toxicity testing procedures specifically aimed for children?

Dr. LANDRIGAN. Yes, we think it does. We think that there needs to be more administration of test chemicals to young animals and that that early administration has to be coupled with lifelong follow-up of the animals so that late effects can be observed.

The CHAIRMAN. On page eight of your report, you say that EPA should "* * * modify its decisionmaking process for setting tolerances so that it is based more on health considerations than on agricultural practices." Why did you come to that conclusion?

Dr. LANDRIGAN. That goes back to the point I made a few minutes ago, that we recognize that in the current law a balancing process is called for in which agricultural considerations are balanced against health. The agricultural considerations have to do with the levels of pesticides that are likely to occur on foods under normal agricultural practices.

We are concerned, however, and we developed specific examples, that there arise situations in which the levels of pesticide permitted on food substantially exceed the reference dose, the so-called acceptable daily intake. The possibility exists therefore that children could consume foods that had so-called legally permissible levels of pesticides on them or in them and yet they would be consuming a dose of pesticide that very substantially exceeds the acceptable daily intake.

We came to the conclusion that this just is not an acceptable situation and we feel that the scales have to be tilted in such a way that health is given precedence.

The CHAIRMAN. Dr. Jackson, you have dealt with public health regulations. Can you give us some examples of how the tolerance-setting process may have undervalued health considerations?

Dr. JACKSON. One example would have been the chemical aldicarb, which was used on food crops that children eat a lot of, potatoes, bananas. They still use it on citrus. This chemical has a tolerance that is high enough that for a child eating amounts of potatoes, even one potato at the tolerance would be encroaching on safety margins, would actually be over the Acceptable Daily Dose.

We have been particularly concerned about the chemicals in the class called cholinesterase inhibitors. These are chemicals that work on the nervous system.

The CHAIRMAN. One of the calls I got from a Farm News reporter was, does this mean if you are having these hearings, we are doing away with all chemicals? As a practical matter, when we are talking about children's exposure, we are really talking about a very small number of chemicals, are we not?

Dr. JACKSON. The issue number one is that if you add up what the Federal Government allows on food and you compare that to what people are allowed to eat, for actually the whole population, the theoretical maximum residue concentration, the amount that the Government permits, the sum of all the tolerances exceeds the Acceptable Daily Intake for several dozen compounds.

It is more extreme in the case of children because they eat more food on a weight basis, but it is true for a large number of compounds, both for adults and children.

One of the points that agriculture has made and a number of the chemical groups have been concerned about is the loss of minor uses.

My current job is head of communicable disease control, although I spent about a dozen years investigating outbreaks of pesticide-related illness. It is interesting. In my new job I have staff answering to me that do vector control in the State of California and at this very moment, my staff are out dusting rodent burrows to control plague in California.

I think one point for the Agriculture Committee is that there are going to be very important uses of pesticides, especially some of these minor uses, that need to be preserved to protect public health and, in some cases, to protect very valuable crops that will really need some of these chemicals to continue production.

The CHAIRMAN. But we are still talking about a very small number of chemicals?

Dr. JACKSON. That is right.

The CHAIRMAN. I was thinking about some of the information that came out this weekend from your report, and watching some of the interviews. I would assume, Dr. Landrigan, you are a pediatrician, there are probably a lot of parents anxiously calling their pediatricians right now.

Now I have heard you give this answer before, but I can hear an anxious parent calling up and saying, what can we feed them? What do we stop feeding them? What do we do?

What answer would you give if one of your patients called you?

Dr. LANDRIGAN. Well, the answer I have already given and will continue to give is that the parents whom I see should continue to

feed their children fruits and vegetables. There is no question in my mind that fruits and vegetables are good for children. They are healthier than many of the alternatives. And moreover, if children learn early in life to take an apple or peach or pear for dessert instead of a sweet, then they establish lifelong habits of good nutrition that will stay with them and will have long-term benefit in terms of health promotion, prevention against heart disease, prevention against cancer.

The last thing I am going to do is tell the parents whom I see to stop feeding their children fruits and vegetables.

The other thing that I am concerned about, though, and I saw it in some of the news shows that I saw last night and the candid interviews with parents in the grocery aisles is this sense of powerlessness that some of the parents seemed to express. They don't know what to do. They realize that washing fruits and vegetables will convey some benefit but probably only limited benefit.

The advice that I would give to parents to deal with that sense of feeling powerless in today's very technical and very large society is that they exercise their democratic right and send letters to people like you to urge you to continue the good work that you are doing.

The CHAIRMAN. They certainly may. With me, they may be preaching to the converted, but I can give them a list of people in both parties whom they may want to write to. [Laughter.]

I have been saying for years on this committee that by focusing on a relatively small number of problem pesticides we could actually cut down the risk to consumers without sacrificing the quality or variety of our fresh fruits and vegetables. I mean, certainly as a consumer I love the variety that we have in this country and I don't want to cut out that variety.

I think we can have both, but I think we have to have a process where we can identify which pesticides pose the greatest risk and then concentrate our resources on finding safer, possibly nonchemical, alternatives.

So I am glad to see that we are finally moving in that direction, and I thank you for your testimony.

I yield to Senator Lugar from Indiana.

Senator LUGAR. Thank you very much, Mr. Chairman.

I appreciate the press conferences of the panel. I saw you, Dr. Landrigan, last evening on the "Nightline" program, and I appreciated your statements stressing that the agricultural and health aspects of this are not necessarily adversaries.

Essentially, this committee has tried to take a look at both aspects over the years, and we have stressed the importance of eating fruits and vegetables, among other things, for basic nutrition and for growth of children and adults as well as being in the best sense of a healthy American diet.

One of the great tragedies of the release of this report would be if, in fact, parents of children all over the country were panicked with regard to feeding their children fruits and vegetables. Whatever may be the health aspects that could come from this study, and I think they will be significantly constructive, they would be overcome by the fact that a lot of people in this country would not be receiving the nutrients that they need.

Dr. LANDRIGAN. Yes, I would agree with that completely, Senator.

Senator LUGAR. I appreciate that statement. I say that this study has supported the fact that we have a reasonably good regulatory system. Regulation is an evolutionary process in which we find out more and we improve upon it.

In preparation for this hearing, I am impressed by the fact that a very, very small fraction, less than 1 percent of all tests of all foods of all kinds have ever indicated pesticide residues that were unacceptable for parents or children.

So we are reducing the risk very, very substantially, and I think the public as a whole needs to know that, that FDA, the EPA, the various people dealing in health are doing a very good job and getting better at it all the time. This is quite different than the view of some that government and regulation and society are collapsing and that people are defenseless in the midst of it all.

Now having said this, let me just probe for a moment about the worst-case scenario. What could be the effects upon children of pesticides that were out of control, that were beyond the tolerances? Is the effect potential cancer or is it damage to the nervous system? As a physician, can you describe what is the worst-case scenario?

Dr. LANDRIGAN. Yes. Well, there are a range of different effects because, of course, the pesticides constitute diverse groups of different chemicals with different toxicities.

Some are acutely toxic. There are some chemicals that produce acute symptoms within minutes or hours of a child or an adult consuming a contaminated fruit, if the contamination level is high enough. Usually those acute symptoms affect the nervous system and are manifested as convulsions or profuse sweating or blurring of vision or gastrointestinal upset.

Probably the more common toxicity, though, is chronic. Depending upon the particular pesticide or combination of them, the chronic toxicities can range from cancer to neurologic impairment to immunologic damage and perhaps to damage to the reproductive and endocrine organs.

Senator LUGAR. Is there evidence of how often this has occurred in the United States?

Dr. LANDRIGAN. Well, the short answer is no, that we do not have good information at all as to how frequently these events occur. We can project, of course—that is the essence of risk assessment—but that is projection.

Senator LUGAR. For instance, my information from the American Cancer Society says that there is no evidence of childhood cancer linked to diet. I think I would qualify that by saying that some physicians would say, as you have, that the chronic aspects of this may be cumulative over a lifetime career of eating.

But nevertheless, in terms of children themselves, I think this is an important point for Americans to understand, that they are not instantly poisoned by these pesticides or do not have toxic death or effects of this variety.

Isn't that your understanding?

Dr. LANDRIGAN. That is important. Another dimension here, of course, is that as physicians we still do not know the causes of many cases of cancer, and there lurks in all of our hearts the feel-

ing, I think, that if we know that a particular chemical or other factor, such as radiation, has the potential to cause cancer, it is prudent to keep exposure down to the lowest possible level in order to prevent cancer, even if it is awfully difficult in the individual case to say that this particular child's or this particular adult's cancer was caused by exposure.

There is a situation here where I believe that it is reasonable as a physician to recommend prudent avoidance, even when we cannot point through epidemiologic studies to the actual accumulation of ill persons.

Senator LUGAR. Dr. Mattison, do you have a comment on this subject?

Dr. MATTISON. Yes, Senator, that is a very good question.

The committee believes very strongly that we need to continuously reassess the techniques that we use for characterizing risks. And in terms of protecting the health of the public, we want to do it in a way that takes advantage of animal data first and then uses that animal data to identify what may be potential risks in human populations.

That is the setting that we are operating in at the present time. There are no data that would suggest that increased risks of cancer, nervous system damage, endocrine damage, or immune damage have occurred from pesticide residues on foods as they are consumed by infants and children, but we believe that as our understanding of these areas of toxicology improves that it is important to charge the regulatory agencies to give greater attention to them.

Senator LUGAR. I appreciate that statement because I think it is profoundly important.

I would agree with both of you that prudence would dictate that even if there is no absolute evidence of cancer in children coming from pesticides, still, it is very, very important, all things considered, to find out much more about connections between pesticide usage and illness. Intuitively we suspect that there are problems there, and as physicians you have clearly observed that there are.

Dr. Jackson, do you have a thought?

Dr. JACKSON. Thank you, Senator.

There is one group of chemicals that we do worry about. These are the so-called cholinesterase inhibitors. These act on nerve enzymes. These are ones that all of you that are farmers are also very worried about, because they are acutely toxic. These are the ones that when the farm workers go into a field too soon and they develop nausea, vomiting, basically pass out in the field, it is because residues of this chemical are too high.

There are about 25 chemicals that work through this effect, and you know them. They range from malathion as a very benign chemical or carbaryl is a very benign chemical right up through extremely toxic ones like parathion and aldicarb.

One of the concerns of the committee was if a child were to sit down and eat a diet that one would reasonable expect a child to eat, and they had a peach over here and a banana over here then at lunch they had a similar assortment and at dinner a similar assortment as well, is it possible because of the way EPA regulates

these chemicals that they could get into the range where there is a problem?

The way EPA regulates these chemicals, even though they all have the same effect, they regulate them independently. It is a little like a doctor prescribing demerol to a patient that is on three other narcotics. EPA needs to regulate these chemicals as a group.

If you look at actual diets that children consume and actual pesticide residues that have been found by FDA when they do food sampling and you array these together, you basically do a mathematical model to compare what the residues are and what children would be expected to eat, you end up in a range for a small percentage of children that begin to encroach on safety margins.

And on page 300 of the report, we talk about the potential for 1.3 percent of children to be in a range where they are exceeding safety margins, eating just 5 pesticides in 8 foods.

Now none of this is to say that we have ever documented an illness in a child from the legal application of pesticides. Illegal applications, yes. On the other hand, it is very hard for a doctor to make the diagnosis. If a baby comes in with a little twitchiness and a little diarrhea, he or she is not going to send off a bunch of bananas for analysis.

But it does speak to the need to go ahead and really ratchet down these tolerances, these legal limits, so that you don't need to even worry about this scenario.

Senator LUGAR. Let me just ask you, Dr. Landrigan, specifically as we try to work our draft into legislation, your committee recommended some procedural changes to risk assessment but your report also indicates that alternative methods to assess the risk should be explored.

Would it be fair to say that a consensus on the methods for assessing risk change from time to time, and for this reason, is it important that the comments made by the committee in its recommendations should be considered for legislation but not necessarily followed to the final degree?

I raise this because in the Kennedy-Waxman bill, it includes specific language regarding risk assessment methods, including a numerical margin of safety values. It strikes me that this might not be the most appropriate method to proceed legislatively, given changes in the state of the art and the fact that you have pointed out that different methods of risk assessment might be explored.

I am really asking a question of how we ought to proceed, but likewise taking off from your report, which is quite specific and yet offers this thought of both the evolution and alternatives. What would your advice be to us as legislators in this regard?

Dr. LANDRIGAN. Well, there is no question that the state of the art in risk assessment has advanced over the past decade, and actually it was a series of studies at the National Academy of Sciences that have been responsible for much of that advancement. The work that we did in this committee builds on that series of previous analyses, particularly on the studies of safe drinking water which have come out over the past 10 years or so.

Indeed, in this analysis here we made some new developments and advances in risk assessment. We made some breakthroughs in

the calculation of the potential future risks of cancer that would result from exposure in early life to children.

Senator LUGAR. Dr. Mattison, if you would incorporate a second question into your answer, your committee also suggested we take a look at food consumption patterns of infants and children and that we work with narrow age groups specifically. The committee mentioned maybe as narrow as a 1-year age group.

Now it has struck some in taking a look at this that perhaps the analysis or the data might not be statistically defensible for groups that small, and I wonder whether this is an ironclad recommendation. Sometimes as legislators we have a tendency to go right into a report of this variety and say, a distinguished committee said to measure this by 1 year, and then we begin to argue whether a year-and-a-half or two would be permissible, with some people having Holy Writ in hand.

What I really want from you is, once again, some charge that you have made some recommendations but that some flexibility might be permissible in trying to get at the general objective.

Dr. MATTISON. Yes, I agree, Senator. I believe that in response both to your earlier question to Dr. Landrigan and in my response to the question that you have asked, we believe based on the data that are available right now that it is scientifically defensible to request those intervals that we recommended.

But we also recognize that as we get better understanding of the way children eat, as we get better understanding of the way that they grow, and as we better characterize the risks to infants and children that the regulatory agencies themselves need to have the flexibility to respond to that continued evolving science base.

I would encourage, personally I would encourage you and your committee members to build in flexibility to allow the agencies to respond to changing understanding of risks to human populations.

Senator LUGAR. As opposed to freezing science, as we have done for a long time with the Delaney Amendment.

Dr. MATTISON. Yes, I agree.

Senator LUGAR. We are still trying to untie ourselves.

Dr. JACKSON. There are two sides to this risk assessment discussion, though. On the one side, you certainly don't want to cast in concrete a technical scientific process. On the other hand, the importance of continuing to refine the science is often used as an excuse to maintain an unacceptable status quo, that the process of really reforming how we decide about pesticides is delayed and delayed because the science, of course, will never be perfect. I think it is time to really cut to the decisions on this.

Senator LUGAR. I agree. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Feingold.

Senator FEINGOLD. Thank you.

Mr. Chairman, Dr. Landrigan and you mentioned earlier that pesticides possibly could affect children in the form of a delayed response manifestation, such as Alzheimer's or forms of dementia. Are there any other types of illness that could be caused by pesticides that would surface in this manner?

Dr. LANDRIGAN. There may be. I want to stress that this is speculative and it is based on animal models and, to this time, not on human studies. But at the National Academy of Sciences, we have considered the possibility that a variety of chronic neurologic diseases might be caused by chemical exposure that becomes manifest in later years.

I mentioned Alzheimer's. But actually the best example probably is in the case of Parkinson's disease. We think that there are converging lines of evidence that chemicals can cause Parkinson's disease. We know that people who mine the metal manganese later develop Parkinson's disease in increased numbers. We know that a chemical that was used as a synthetic heroin, called MPTP, has caused cases of Parkinson's disease, sometimes terribly severe cases.

And more and more, we think that there may be other cases of Parkinson's whose precise causation we don't know, that may be caused by chemical exposure, then dementia, then a third neurologic disease referred to as amyotrophic lateral sclerosis, known frequently as Lou Gehrig's disease. There is the sense that some cases of that might be caused by chemicals, although other cases are probably genetic in origin.

We know full well, based on extensive human and animal experience, that early exposure to various chemicals can cause cancer. Cancer is actually the best grounded here.

And then we know that some chemicals can cause male sterility. One particular pesticide, DBCP, and a second one, ketone, have both been shown capable of reducing sperm counts in male workers, and we think there may be others not yet adequately documented.

Then lastly, there is the issue of endocrine toxicity and immunologic toxicity, a bit more speculative but not beyond the scope of reason.

Senator FEINGOLD. I had an interest in the general question of irreversible dementias, and you have mentioned Alzheimer's and Parkinson's. Would all irreversible dementias potentially be involved in this, or is it just particular ones?

Dr. LANDRIGAN. Potentially, yes sir, some cases of each. I think that what we will find, what we are already finding is that dementia is actually a family of diseases with one terribly distressing symptom in common, namely loss of memory and loss of cognition. We will probably find, just as we now know for cancer, that there are many different causes, but chemical factors will almost surely be counted among those causes.

Senator FEINGOLD. Thank you.

Another question has to do with one of the most important recommendations of the study—the call for better data on exposure residues and improved information on the effects of pesticides in infants and children, as everyone has mentioned. The committee recommends that better risk assessment methods be developed to determine the magnitude of these impacts on children, but I assume that doing that would consume large amounts of time and resources.

Given the length of time required for the NAS committee to finish this study, what would be an appropriate time frame for us

to look at for the relevant Federal agencies to actually implement these recommendations?

Dr. LANDRIGAN. Well, I think it is beyond my expertise to speculate on how long it might take the agencies to do a survey, but what I could do is draw a distinction here between changes that we think can be made in the short term, more or less in the here and now, and those that clearly will require more time.

The change in regulatory posture that we have been talking about in the last hour or so, the need, in our opinion, to put considerations of protecting health first is something that the Administrator of EPA in concert with the Director of the Food and Drug Administration and the Secretary of Agriculture could do rather promptly, and indeed from the press release that we read over the weekend, there seems to be a clear sign that the directors of these three agencies are, in fact, already taking steps in the proper direction, steps that all of us on the committee hope now will be continued, now that they have begun the process.

And those changes in what you might call regulatory philosophy within the agency take little time at all to accomplish. They take time to play out, of course, as they are applied to particular chemicals, but the change in philosophy can be done almost with the stroke of a pen.

By contrast, of course, better animal testing, the conduct of national surveys that collect better information than is presently collected is clearly going to be a multiyear process.

In the case of animal toxicity testing, I had the opportunity on Friday to talk to Dr. Kenneth Olden, Director of the National Institute of Environmental Health Sciences. That is the agency within the Public Health Service that has responsibility for the National Toxicology Program. He told me that they are already taking steps to improve their toxicity testing procedures to focus more than before on toxicity in the young. That is clearly a direction in which the agency should be encouraged to proceed further.

Dr. SHINE. Senator, one of the areas that as an observer of this process I have been encouraged by is the fact that over the weekend the three principal agencies were talking to each other and were talking about the notion that they would try to make their data bases compatible, that they would try to analyze the data in a way that was uniformly useful to everyone, and I think that is going to be an important element in terms of the implementation that you have asked about.

Dr. JACKSON. Senator, a couple of things really surprised me as I went through this study. One which I have just mentioned is I knew that tolerances, the legal limits for pesticide residues in food, were agriculturally set and not health set, but I was still surprised at how far apart those numbers were.

But the second thing that surprised me as I did this study, as we worked on this study, was somehow I thought there was a giant computer somewhere that knew what the chemical residues of chemical X, Y, and Z in crops A, B, and C were, and what we concluded is it is almost a tower of Babel.

You have the Food and Drug Administration data set, you have a USDA data set, you have an EPA data set, you have a supermarket industry data set, you have the chemical companies data set,

and I know there have been a lot of complaints about only 1 percent of food being tested and all this sort of thing.

I don't think—this is a personal opinion, not a committee opinion—that we need to increase the numbers of samples but we really do need to increase how we think about it, really to make it random, to really collect the data well, to use the best possible lab tests.

We were looking at data sets where they weren't keeping track of all the times that there was no finding, where there was a zero finding, and we had other data sets where we didn't know how good the lab test was, did it go down to 1 part per million or 10 parts per billion. So really making that data collection system rational and useful for all the agencies and for the public would be a big step forward, and I don't think it would cost that much.

Senator FEINGOLD. Mr. Chairman, if I may, one more question?

The CHAIRMAN. Of course.

Senator FEINGOLD. In the study you have talked about the nondietary sources of pesticide residues such as air and dirt, pets, and the need to consider those sources when we estimate the risks of pesticides to children. This may be answered in your report and I apologize if I have not read it all. I am curious as to how we would go about gathering that kind of data. It seems like it would have substantial geographic specificity, which would make it rather difficult.

Dr. JACKSON. There have already been a number of quite good surveys on nonfood, nonoccupational pesticide exposures. Part of the problem is that when the EPA sets a drinking water standard, they assume that you are getting 80 percent of your chemicals somewhere else than drinking water. They don't use up all your acceptable daily intake in setting a drinking water standard.

One problem in the setting of food standards is they use up the acceptable daily intake or the reference dose. They don't leave any margin left over for the, for example, the baby rolling on a newly-treated lawn by a chemical company or a rug where flea bombs have been set off in a room to control fleas. So there does need to be a margin left over, a margin of safety for nonfood exposures. They are extensive.

Senator FEINGOLD. Thank you for your answers, and thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

Senator Daschle.

Senator DASCHLE. Thank you, Mr. Chairman.

I guess I would like to clarify what reasons you would give for not having better risk assessment and tolerance level information today. You called attention to the fact that our data just isn't very good. I think Dr. Jackson may have put his finger on part of the problem. That is, the Babel, as he called it, between agencies attempting to understand better the data currently available to us.

But is it a lack of priority? Is it a lack of that communication? What reasons would you give for the fact that we are not where we should be?

Dr. MATTISON. Well, I think that there are probably two. One is the agencies have substantial regulatory responsibility. That is, to conduct tests with a specific goal of assuring that foods don't

exceed what are considered appropriate limits of pesticide residues. So a large amount of their energy and effort is focused on that aspect as opposed to a more scientifically designed strategy for characterizing exposures across the total population.

The second is risk assessment as we are talking about it in quantitative terms is a relatively young science. The steps, the framework for doing risk assessment were laid out in a National Academy report which was published in 1984. So in less than a decade, we are beginning to ask questions in a much more sophisticated way than were possible at the time that that original report was published.

I think those are two factors that put us into a position where we certainly identify areas that need to be improved but it is on the basis of the understanding that we have developed over less than a decade of activity.

Dr. JACKSON. I think that we would like to mention that we received excellent cooperation from the Federal agencies that were involved, USDA, EPA, FDA, and yet I think any member of this committee is aware that the degree of dialogue and working together among the agencies has not always been as close or as coherent as it could be, and I think it is a very positive step forward, the announcement we heard last week.

Senator DASCHLE. Just asking the question in another way, to what extent were you able to detect the degree of cross pressures, researchers maybe feeling between what appears at some times to be conflicting goals of consumer protection and agricultural production? How much of that cross pressure is evident, if at all? Or is the research community created in such a way where you have consumer protection research done independently of agricultural production research so there isn't any juxtaposition of the two goals?

Dr. LANDRIGAN. Well, I think one of the interesting things that took place, Senator, in this committee, and Dr. Shine alluded to it at the beginning, was the fact that we had a group of 14 people with very diverse backgrounds, ranging from food science and chemistry to pediatrics who also represented a range of political and social points of view, who worked together for 5 years on this report and came to unanimous conclusions with no dissenting votes. Unlike some reports from the National Academy that have minority reports or dissents attached, this report contained no such dissent or minority opinion.

I think it attests to the fact that if you get reasonable people together and grapple with these problems, it is possible at least some of the time to reach unanimity and to come up with clear ideas.

There is no question, of course, that there is polarization in our society around some of these issues. We all know that. But I am heartened by the collaboration and the convergence that we achieved—and I would say that it is convergence without dilution. We really came down four-square for a position that is protective of public health, one that I feel very proud as a pediatrician and as a person who has spent most of his adult life doing public health. I think it is perhaps a model for what can be achieved in this area and it is the kind of thing that needs to be encouraged.

On the current national scene, the point that we just addressed, the fact that the three principal agencies have come together and pledged publicly to work together in a way that we haven't seen in a long time, if ever, is very good news.

Dr. SHINE. I should also comment, Senator, that the Institute of Medicine and the Academy have been working very hard to create this kind of an interaction beyond this area. We have recently established a food forum with representatives of industry, of agencies, and of the academic community and consumer groups. That forum has a subsection which is looking at issues of food safety, and it is an attempt to bring the various points of view together.

I am hoping that this document will be another step in terms of that kind of communication and that kind of facilitation. So we see this as part of a larger effort.

Dr. JACKSON. Senator, I suspect that your committee will have to deal with one of the great dichotomies around pesticides, which is that old chemicals operate under a code where they are innocent until proven guilty and the new chemicals have to prove safety.

The old code leads to problems where chemicals that really are problematic and ought to be replaced with more scientific and more precise, better-designed chemicals stay on the market and stay on the market too long, and it really creates a disruption. Farmers don't know whether they have got it or they don't have it, whether they can use it or they cannot use it. These are situations that are very unstable in the sense of you don't know what kind of politics or what kind of media play are going to come out of them.

We really have to create a level playing field for both the old and the new chemicals so that farmers can get new instruments to control the problems that they have and get rid of some of the chemicals that have been around too long and really would never get on the market today.

Senator DASCHLE. Let me just ask one last question with regard to this mutual statement of intent. You have obviously had the opportunity to review the priorities set in agriculture research today as it relates to both productivity as well as consumer protection.

To what extent, given this statement of intent to work together, to try to accomplish the objectives that you have outlined here, to what extent will that require divergence from the priorities that exist today? How much change is going to be required? Are we talking fairly significant change from the agricultural research community or is it moderate in its scope?

Dr. LANDRIGAN. Well, there are clearly going to have to be more resources put into the testing of toxicity of chemicals, and there may also need to be incorporated into agricultural education some changes in attitude.

Let me give you an analogy from a field that is closer to my professional work.

Senator DASCHLE. Could you also, as you do, give us some guidelines that you could recommend as we consider how we implement this?

Dr. LANDRIGAN. Yes, I would be pleased to, Senator. I have a specific example in mind.

I served for a number of years with the U.S. Public Health Service at the National Institute for Occupational Safety and Health.

One of the things that we were concerned about in that agency was the fact that people were graduating from engineering schools, going to work as practicing engineers, working in the chemical industry or working in civil engineering who knew all about concrete and all about chemical reactors but almost nothing about the possible health risks that could accrue to people that worked with those materials or the citizens that lived in the vicinity.

And it was this blind spot in engineering training that led our institute to initiate a program for providing training in occupational health and safety at a basic level to engineering students. Indeed, it is now required in engineering certification, I am told, that the students be able to demonstrate a mastery of basic principles in that area.

There may be enhanced need for a very similar cross-fertilization in agricultural training. People who get degrees in agriculture need to know in a systematic, knowledgeable, scientific fashion about the hazards of the pesticides with which they are going to work when they practice farming in their adult lives, the chemicals to which they and their children are going to be exposed so that they can take rational steps to reduce their exposure and to reduce the concentrations that will be applied on the crops.

Senator DASCHLE. I thank the panel and I thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Cochran, you have been one who has worked awfully hard on this committee over the years on this subject and I am delighted to have you here with us today.

Senator COCHRAN. Thank you very much, Mr. Chairman.

Mr. Chairman, like you, I am interested in what we can do in response to this report to help implement or to help improve the situation so that we will have better information that is disseminated in a more effective and understandable way to the general public. I think that is one of the big challenges that we face in this area.

I was noticing on page 362 of your report there is a specific recommendation that you include which speaks to this issue, and you suggest that the use of risk distributions rather than a point estimate such as a mean, median, or other definitive estimate should be used where possible to provide a more complete characterization of risk.

That strikes me as something that we really do need to concentrate some attention and effort, particularly in specific instances where suggestions have been made by someone who may not have all the facts that a certain chemical or a certain food supply may be dangerous for human consumption, and expert testimony is required to set the record straight.

I recall when Meryl Streep came before our committee and suggested that all the apples in our food supply were at risk, and our school children couldn't eat apples because the school systems took them off the serving lines.

We convened a hearing with the FDA Commissioner, the Department of Agriculture's chief expert in this area, EPA's chief expert, and we talked about it. We found out that the risk characterization had been inaccurate. But their comments never got out. Their as-

sessment of the risk and their characterization of risk was never really communicated very effectively, but the risk itself that had earlier come to the attention of the public had sort of sunk in and was considered the fact.

How do we deal with that kind of situation? Do you try, in your assessment, to suggest how the Government can better establish credibility in communicating or characterizing the risks in these situations?

Dr. LANDRIGAN. Yes, that is a very important question, Senator, and in many respects cuts to the heart of this whole report.

The Alar case, of course, was a difficult one because the chemical Alar and its metabolic breakdown product, hydrazine, were unquestionably human carcinogens. They have been recognized as definite animal carcinogens by the World Health Organization and as probable human carcinogens by the World Health Organization, so there was no question about the toxicity of that particular chemical.

But fortunately, by the time we undertook this analysis, Alar was pretty much off the market and we just did not consider it in our calculations at all.

What we did here in that last recommendation that you have highlighted is that we have laid out for the Federal agencies in our book, and it is mostly in chapter eight, a very detailed methodology for looking at the whole range of risks that extend across the population, and indeed, we have taken it a step further.

We wanted to make it as feasible as possible for the agencies to proceed with this new approach to risk assessment. Therefore we are actually providing them this week the computer software necessary to do those risk calculations. Dr. Krewsky and Dr. Wargo, who are our mathematicians on the committee, developed this software with some technical support from the National Academy. That software is being made available to the agencies so that they can really look at the extent of risk.

I think the great gain that will result from the agencies employing this software or maybe its descendant, if they can refine it further, is that they will avoid unseemly surprises such as happened in the case of Alar. They will be able to look at risks in a rational fashion, plot the extent of risk that extends across the population, and take reasonable actions before they blow up and become crises.

Senator COCHRAN. Dr. Mattison.

Dr. MATTISON. Senator, I would like to respond to the second part of the question you asked, relating to risk communication.

That is an area that I think does need substantially greater attention. We need to understand how to better communicate risks across the diverse populations that exist in the United States in a way that is both understandable and can be factored into decision making by individual citizens in the United States, and that is something that has not been well done.

You can look across a range of types of issues where individuals have to make decisions, from nutrition to immunizations to a range of other factors, and I think you will find that the way we communicate both risks and benefits deserves much greater attention.

Senator COCHRAN. Yes?

Dr. JACKSON. Senator, I had the pleasure of testifying before this distinguished committee on that March 16, 1989 hearing. I testified between Ms. Streep and the Uniroyal representative, and I testified on behalf of the Academy of Pediatrics.

In my testimony, I said we saw no immediate or acute hazards. People should continue to eat fruits and vegetables, continue your diet, but on a long-term basis these exposures were really unacceptable.

Dr. Mattison has talked about risk communication, and one aspect of risk communication is outrage. People become outraged when they feel like they have been badly treated. This was a chemical that was used for 25 years without an adequate carcinogenicity data base. They hadn't done the cancer studies on rats and mice to show that it was a problem or not a problem.

And part of what comes out of looking at that episode is a need for a strong, effective FIFRA, Federal Insecticide, Fungicide, and Rodenticide Act, that really is going to deal with these and be implemented well.

Senator COCHRAN. I noticed the report deals mostly with administrative agency actions that should be improved. For example, agencies should increase the data base they have for food consumption, better coordinate data on pesticide residues in foods, and modify testing of pesticides.

If all of these are implemented, no legislation would really be required. It seems that these are improvements in the regulatory process that could be undertaken without the need for legislation, as I understand that.

Do you agree with that?

Dr. LANDRIGAN. As a pediatrician, Senator, I am not sure I feel qualified to answer the question.

There is no doubt that the agencies can make a lot of progress implementing the recommendations that we have made here. As Dr. Jackson pointed out a few minutes ago, the implementation of these recommendations need not be prohibitively expensive. In many cases, for example, the agencies are collecting data, they just are not collecting it very wisely. We think that with coordination among the agencies they can collect as much information but collect it smarter and get a lot more bang for their dollar.

But whether new regulation is needed, I believe that is beyond my purview and respectfully I would decline to answer that. [Laughter.]

Senator COCHRAN. An "I don't know" is okay.

The CHAIRMAN. Incidentally——

Senator COCHRAN. I am not going to force you to tell us something you don't know. [Laughter.]

We talk about things we don't understand a lot. [Laughter.]

The CHAIRMAN. Yes, but we are expected to.

Senator COCHRAN. Oh.

The CHAIRMAN. We are expected to. I mean, these are scientists. If you would yield just for one point of correction——

Senator COCHRAN. Yes.

The CHAIRMAN. There have been discussions of a movie star or somebody outside the scientific world testifying regarding Alar

before this committee. It wasn't this committee, it was another committee.

Senator COCHRAN. Well, I was on it, anyway.

The CHAIRMAN. I think it was the Labor Committee. We had some scientific testimony, as I recall, but I think that the testimony you referred to, Dr. Jackson, was before another committee, maybe some of the same members. As chairman, I prefer having scientists.

Dr. JACKSON. Thank you for correcting me, Senator.

The CHAIRMAN. Senator Cochran.

Senator COCHRAN. That did kind of cast an aspersion. I didn't mean to do that.

The CHAIRMAN. No, I understand.

Senator COCHRAN. One thing that does strike me is you are talking about coordinating information, having a computer, for example, that could tell us some of the things that we need to know across Government agency boundaries and not lines of jurisdiction. That, to me, is certainly something that ought to be considered.

One of our Senators has introduced legislation to create a new office of food inspection and safety assessment, in effect a food safety czar would be created under this legislation.

What is your impression of this one-stop assessment and characterization of risks in our food supply? Would that be an appropriate step in the right direction?

Dr. LANDRIGAN. I don't know, Senator. That is the first I have heard about that and I haven't had time to think about it. Sorry.

Senator COCHRAN. One suggestion was made earlier about how this report has taken so long to produce. I am not one to criticize for that reason, because we wanted a thorough and factual and reliable report. I assume that is what we have here which all of you have worked hard to produce.

Somebody suggested that the reason that it was overdue or took so long to really come out was that industry was pressuring you to water it down. Is there any truth in that?

Dr. LANDRIGAN. No sir, none whatsoever. We worked hard, we worked coherently, and there was no evidence whatsoever of any sort of conspiracy or effort to halt us.

Dr. SHINE. Senator, I had the opportunity, having come to the Academy last July to review the activities with regard to this project and have followed them over the last 12 months, and I found no evidence that any of those allegations had any basis.

Senator COCHRAN. Thank you.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you.

It is obvious from this testimony that it is not just the kind of chemicals we are exposed to but when we are exposed to them. I know it has been stated a number of times here, but it doesn't hurt to restate it.

The chemicals that each of us as adults can be exposed to at really no risk may pose a risk in young children when their neurological systems and immune systems are being developed. That combines with the fact that there are certain things they eat a lot more of, there are certain fruits and vegetables that as adults we don't make virtually a full meal on but as infants we may.

I am wondering, does this mean that EPA should include an additional safety factor in its risk assessment procedures to account for the effect of exposures early on in life?

Dr. LANDRIGAN. Yes, Mr. Chairman. We made a specific recommendation in the report that the EPA ought to consider imposing an additional safety factor.

At the present time, they impose two safety factors, each tenfold, when they go from animal test data to setting human acceptable daily intakes, reference doses. The first tenfold factor is to go from animals to human, and the second tenfold is to account for variations among adult humans.

We are suggesting to the agencies that they consider imposing a third tenfold factor so that the total margin of safety would be 10 times 10 times 10, so a thousandfold in setting the reference doses. And we recommend that they do that unless good testing has been done, good testing which provides specific evidence that there is no difference in toxicity between adults and infants.

As a matter of fact, the agency is already doing that to some extent. So what we are doing is ratifying and blessing what they are doing and suggesting that they extend it further.

The CHAIRMAN. I have been trying to catch up on this report. We in Congress didn't receive it until after it had been reviewed, I guess, in the New York Times over the weekend, and I appreciate that we were on the distribution list to come almost immediately or at least 24 hours after it was sent to the press. In any event, I am delighted to have it get as wide circulation as possible, but I want to make sure I am understanding it.

Do I read it correctly that because of the cumulative effect that pesticides may have—and perhaps, Dr. Jackson, I should ask you this—that on any given day there may be over 3,500 children exposed to tenfold the acceptable level of pesticides?

Dr. JACKSON. These were calculations, I had mentioned them earlier, they are around page 300 in the report, Senator, where we look at actual residues of organophosphates, chemicals that inhibit a nervous enzyme and actual food consumption data and mathematically construct almost 10 million days of consumption for a mathematically-constructed population of 2-year-olds.

And in that population, we do find or we can calculate that there would be that many children, in the range of 3,500. These are not numbers that are perfect in any way, but our intent here is to really tell the agency, this is important. You need to pay attention to this.

People have been saying for a while, we are worried about additive risks, but this is the first time it has been documented in a report such as this, saying when you start to regulate these you cannot regulate each one of these chemicals as if there is no other chemical being used that has the same effect. You have to look at them as a group.

The CHAIRMAN. Well, I was struck by the same thing Dr. Landrigan said earlier, that unlike so many of these kind of reports there was no dissenting report, not even a "concurring, but" kind of report, where someone says, " Well, I concur with it but for different reasons and whatever." It just comes across, I understand, with

uniformity that the acceptable levels that we talk about in Government standards are not set with children in mind.

Is that safe to say, that there is absolutely no dissention on that among the members?

Dr. LANDRIGAN. Yes, that was the very clear and unanimous conclusion of the committee and one on which we formally voted at our last meeting in January of this year.

The CHAIRMAN. And it was unanimous?

Dr. LANDRIGAN. Yes sir, it was.

The CHAIRMAN. Dr. Mattison, I think you were trying to say something. I saw you reaching for the mike.

Dr. MATTISON. I just wanted to respond to the question that you addressed to Dr. Jackson.

The CHAIRMAN. Please.

Dr. MATTISON. We need to put some warnings around those estimates of children at risk because we have serious concerns about the quality of the data, and, in fact, one of our recommendations is that substantially greater attention be given to the way that the data is collected so that characterization of risks can be done in an accurate way.

Dr. JACKSON. One way that you really could get a better estimate of this is if the lab tests were better, because if the lab test cuts off at a very sensitive level, you read that as near-zero when you do the analysis. If the lab tests are better and you get much lower sensitivities of the lab test, you then end up predicting lower levels of risk. So it does argue for better analysis of the food.

The CHAIRMAN. Thank you.

Senator Lugar.

Senator LUGAR. Mr. Chairman, I have no more questions. I just want to express appreciation, again, to the panel for a very good hearing. I think we have a much better understanding of your report.

The CHAIRMAN. Thank you. Gentlemen, I do appreciate what you have done. I think that it has turned out to be a tremendous service.

I speak of my children, the youngest is now a student at the University of Vermont, a former Marine, so I can't really think of him as a child. The other two are even older and married. Although I assume some day I'll be a grandparent, I listened with some jealousy as some of my other panel members spoke of that.

But I would hope that before that day comes we might have a better idea or better standards set or alternatives, and I don't say that facetiously.

Dr. Landrigan, just to go back to you a moment, I mean, you are a pediatrician and you see so many children in their formative years and do see everything from making sure they get their measles shots.

My feeling is that most parents want to do what is right for their children in diet, in bringing them up, and all, but none of us are experts. I mean, we can't pick up a fruit or a vegetable or something else that we know our child should be eating and say, aha, this one is really safe for them or this one is not.

But I think also we can do something as a government to help that, to guarantee that level of safety, but also to be helpful for

those who produce our food and fiber. We are blessed in this country with the abundance of food and variety of food that is not matched anywhere else in the world. The safety of our food is unmatched anywhere else in the world. But I think that we can do better, I think we will do better for our children but also for those who produce the food and fiber because they are usually on the first line of it.

I know you spent a great deal of time on this. I applaud the amount of pro bono hours that went into this report. I think it shows an enormous sense of responsibility on the part of everybody who did that. But I also think the applause will probably come from a lot of parents and a lot of as-yet-unborn children, and I thank you very, very much.

Dr. LANDRIGAN. Thank you, Mr. Chairman. Thank you, Senator.

The CHAIRMAN. The hearing is adjourned.

[Whereupon, at 12:14 p.m., the committee was adjourned.]

APPENDIX

[The Executive Summary of the National Academy of Sciences report follows:]

PESTICIDES in the DIETS OF INFANTS AND CHILDREN

Committee on Pesticides in the Diets of
Infants and Children

Board on Agriculture
and
Board on Environmental Studies and Toxicology

Commission on Life Sciences

National Research Council

NATIONAL ACADEMY PRESS
Washington, D.C. 1993

Executive Summary

PESTICIDES ARE USED WIDELY in agriculture in the United States. Their application has improved crop yields and has increased the quantity of fresh fruits and vegetables in the diet, thereby contributing to improvements in public health.

But pesticides may also cause harm. Some can damage the environment and accumulate in ecosystems. And depending on dose, some pesticides can cause a range of adverse effects on human health, including cancer, acute and chronic injury to the nervous system, lung damage, reproductive dysfunction, and possibly dysfunction of the endocrine and immune systems.

Diet is an important source of exposure to pesticides. The trace quantities of pesticides that are present on or in foodstuffs are termed residues. To minimize exposure of the general population to pesticide residues in food, the U.S. Government has instituted regulatory controls on pesticide use. These are intended to limit exposures to residues while ensuring an abundant and nutritious food supply. The legislative framework for these controls was established by the Congress through the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and the Federal Food, Drug, and Cosmetic Act (FFDCA). Pesticides are defined broadly in this context to include insecticides, herbicides, and fungicides.

Tolerances constitute the single, most important mechanism by which EPA limits levels of pesticide residues in foods. A tolerance is defined as the legal limit of a pesticide residue allowed in or on a raw agricultural commodity and, in appropriate cases, on processed foods. A tolerance must be established for any pesticide used on any food crop.

Tolerance concentrations are based primarily on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal conditions of agricultural use. Their principal purpose is to ensure compliance with good agricultural practice. Tolerances are not based primarily on health considerations.

This report addresses the question of whether current regulatory approaches for controlling pesticide residues in foods adequately protect infants and children. The exposure of infants and children and their susceptibility to harm from ingesting pesticide residues may differ from that of adults. The current regulatory system does not, however, specifically consider infants and children. It does not examine the wide range of pesticide exposure patterns that appear to exist within the U.S. population. It looks only at the average exposure of the entire population. As a consequence, variations in dietary exposure to pesticides and health risks related to age and to such other factors as geographic region and ethnicity are not addressed in current regulatory practice.

Concern about the potential vulnerability of infants and children to dietary pesticides led the U.S. Congress in 1988 to request that the National Academy of Sciences (NAS) appoint a committee to study this issue through its National Research Council (NRC). In response, the NRC appointed a Committee on Pesticide Residues in the Diets of Infants and Children under the joint aegis of the Board on Agriculture and the Board on Environmental Studies and Toxicology.

The committee was charged with responsibility for examining scientific and policy issues faced by government agencies, particularly EPA, in regulating pesticide residues in foods consumed by infants and children. Specifically, the committee was asked to examine the adequacy of current risk assessment policies and methods; to assess information on the dietary intakes of infants and children; to evaluate data on pesticide residues in the food supply; to identify toxicological issues of greatest concern; and to develop relevant research priorities. Expertise represented on the committee included toxicology, epidemiology, biostatistics, food science and nutrition, analytical chemistry, child growth and development, and pediatrics.

The committee was not asked to consider toxicities resulting from exposures to microorganisms (bacteria and viruses) or from other naturally occurring potential toxins. It was not asked to weigh the benefits and risks to be derived from a plentiful and varied food supply against the potential risks resulting from pesticide exposure. It was not asked to assess the overall safety of the food supply.

In this report, the committee considered the development of children from the beginning of the last trimester of pregnancy (26 weeks) through

18 years of age, the point when all biological systems have essentially matured.

CONCLUSIONS

Age-Related Variation in Susceptibility and Toxicity

A fundamental maxim of pediatric medicine is that children are not "little adults." Profound differences exist between children and adults. Infants and children are growing and developing. Their metabolic rates are more rapid than those of adults. There are differences in their ability to activate, detoxify, and excrete xenobiotic compounds. All these differences can affect the toxicity of pesticides in infants and children, and for these reasons the toxicity of pesticides is frequently different in children and adults. Children may be more sensitive or less sensitive than adults, depending on the pesticide to which they are exposed. Moreover, because these processes can change rapidly and can counteract one another, there is no simple way to predict the kinetics and sensitivity to chemical compounds in infants and children from data derived entirely from adult humans or from toxicity testing in adult or adolescent animals.

The committee found both quantitative and occasionally qualitative differences in toxicity of pesticides between children and adults. Qualitative differences in toxicity are the consequence of exposures during special windows of vulnerability—brief periods early in development when exposure to a toxicant can permanently alter the structure or function of an organ system. Classic examples include chloramphenicol exposure of newborns and vascular collapse (gray baby syndrome), tetracycline and dysplasia of the dental enamel, and lead and altered neurologic development.

Quantitative differences in pesticide toxicity between children and adults are due in part to age-related differences in absorption, metabolism, detoxification, and excretion of xenobiotic compounds, that is, to differences in both pharmacokinetic and pharmacodynamic processes. Differences in size, immaturity of biochemical and physiological functions in major body systems, and variation in body composition (water, fat, protein, and mineral content) all can influence the extent of toxicity. Because newborns are the group most different anatomically and physiologically from adults, they may exhibit the most pronounced quantitative differences in sensitivity to pesticides. **The committee found that quantitative differences in toxicity between children and adults are usually less than a factor of approximately 10-fold.**

The committee concluded that the mechanism of action of a toxicant—how it causes harm—is generally similar in most species and across age

and developmental stages within species. For example, if a substance is cytotoxic in adults, it is usually also cytotoxic in immature individuals.

Lack of data on pesticide toxicity in developing organisms was a recurrent problem encountered by the committee. In particular, little work has been done to identify effects that develop after a long latent period or to investigate the effects of pesticide exposure on neurotoxic, immunotoxic, or endocrine responses in infants and children. The committee therefore had to rely mostly on incomplete information derived from studies in mature animals and on chemicals other than pesticides.

The committee reviewed current EPA requirements for toxicity testing by pesticide manufacturers, as well as testing modifications proposed by the agency. In general, the committee found that current and past studies conducted by pesticide manufacturers are designed primarily to assess pesticide toxicity in sexually mature animals. Only a minority of testing protocols have supported extrapolation to infant and adolescent animals. Current testing protocols do not, for the most part, adequately address the toxicity and metabolism of pesticides in neonates and adolescent animals or the effects of exposure during early developmental stages and their sequelae in later life.

Age-Related Differences in Exposure

Estimation of the exposures of infants and children to pesticide residues requires information on (1) dietary composition and (2) residue concentrations in and on the food and water consumed. **The committee found that infants and children differ both qualitatively and quantitatively from adults in their exposure to pesticide residues in foods.** Children consume more calories of food per unit of body weight than do adults. But at the same time, infants and children consume far fewer types of foods than do adults. Thus, infants and young children may consume much more of certain foods, especially processed foods, than do adults. And water consumption, both as drinking water and as a food component, is very different between children and adults.

The committee concluded that differences in diet and thus in dietary exposure to pesticide residues account for most of the differences in pesticide-related health risks that were found to exist between children and adults. Differences in exposure were generally a more important source of differences in risk than were age-related differences in toxicologic vulnerability.

Data from various food consumption surveys were made available to the committee. In analyzing these data, the committee found it necessary to create its own computer programs to convert foods as consumed into their component raw agricultural commodities (RACs). This analytic ap-

proach facilitated the use of data from different sources and permitted evaluation of total exposure to pesticides in different food commodities. For processed foods, the committee noted that effects of processing on residue concentrations should be considered, but that information on these effects is quite limited. Processing may decrease or increase pesticide residue concentrations. The limited data available suggest that pesticide residues are generally reduced by processing; however, more research is needed to define the direction and magnitude of the changes for specific pesticide-food combinations. The effect of processing is an important consideration in assessing the dietary exposures of infants and young children, who consume large quantities of processed foods, such as fruit juices, baby food, milk, and infant formula.

Although there are several sources of data on pesticide residues in the United States, the data are of variable quality, and there are wide variations in sample selection, reflecting criteria developed for different sampling purposes, and in analytical procedures, reflecting different laboratory capabilities and different levels of quantification between and within laboratories. These differences reflect variations in precision and in the accuracy of methods used and the different approaches to analytical issues, such as variations in limit of quantification. There also are substantial differences in data reporting. These differences are due in part to different record-keeping requirements, such as whether to identify samples with multiple residues, and differences in statistical treatment of laboratory results below the limit of quantification.

Both government and industry data on residue concentrations in foods reflect the current regulatory emphasis on average adult consumption patterns. The committee found that foods eaten by infants and children are underrepresented in surveys of commodity residues. Many of the available residue data were generated for targeted compliance purposes by the Food and Drug Administration (FDA) to find residue concentrations exceeding the legal tolerances established by the EPA under FFDCA.

Survey data on consumption of particular foods are conventionally grouped by broad age categories. The average consumption of a hypothetical "normal" person is then used to represent the age group. However, in relying solely on the average as a measure of consumption, important information on the distribution of consumption patterns is lost. For example, the high levels of consumption within a particular age group are especially relevant when considering foods that might contain residues capable of causing acute toxic effects. Also, geographic, ethnic, and other differences may be overlooked.

To overcome the problems inherent in the current reliance on "average" exposures, the committee used the technique of statistical convolution (i.e., combining various data bases) to merge distributions of food consumption

with distributions of residue concentrations. This approach permits examination of the full range of pesticide exposures in the U.S. pediatric population. As is described in the next section, this approach provides an improved basis over the approach now used for assessing risks for infants and children.

A New Approach to Risk Assessment for Infants and Children

To properly characterize risk to infants and children from pesticide residues in the diet, information is required on (1) food consumption patterns of infants and children, (2) concentrations of pesticide residues in foods consumed by infants and children, and (3) toxic effects of pesticides, especially effects that may be unique to infants and children. If suitable data on these three items are available, risk assessment methods based on the technique of statistical convolution can be used to estimate the likelihood that infants and children who experience specific exposure patterns may be at risk. To characterize potential risks to infants and children in this fashion, the committee utilized data on distributions of pesticide exposure that, in turn, were based on distributions of food consumption merged with data on the distribution of pesticide residue concentrations. The committee found that age-related differences in exposure patterns for 1- to 5-year-old children were most accurately illuminated by using 1-year age groupings of data on children's food consumption.

Exposure estimates should be constructed differently depending on whether acute or chronic effects are of concern. Average daily ingestion of pesticide residues is an appropriate measure of exposure for assessing the risk of chronic toxicity. However, actual individual daily ingestion is more appropriate for assessing acute toxicity. Because chronic toxicity is often related to long-term average exposure, the average daily dietary exposure to pesticide residues may be used as the basis for risk assessment when the potential for delayed, irreversible chronic toxic effects exists. Because acute toxicity is more often mediated by peak exposures occurring within a short period (e.g., over the course of a day or even during a single eating occasion), individual daily intakes are of interest. Examining the distribution of individual daily intakes within the population of interest reflects day-to-day variation in pesticide ingestion both for specific individuals and among individuals.

Children may be exposed to multiple pesticides with a common toxic effect, and estimates of exposure and of risk could therefore be improved by accounting for these simultaneous exposures. This can be accomplished by assigning toxicity equivalence factors to each of the compounds having a common mechanism of action. Total residue exposure is then estimated

by multiplying the actual level of each pesticide residue by its toxicity equivalence factor and summing the results. This information may be combined with data on consumption to construct a distribution of total exposure to all pesticides having a common mechanism of action. To test this multiple-residue methodology, the committee estimated children's acute health risks resulting from combined exposure to five members of the organophosphate insecticide family. This was accomplished by combining actual food consumption data with data on actual pesticide residue levels.

Through this new analytical procedure, the committee estimated that for some children, total organophosphate exposures may exceed the reference dose. Furthermore, although the data were weak, the committee estimated that for some children exposures could be sufficiently high to produce symptoms of acute organophosphate pesticide poisoning.

Compared to late-in-life exposures, exposures to pesticides early in life can lead to a greater risk of chronic effects that are expressed only after long latency periods have elapsed. Such effects include cancer, neurodevelopmental impairment, and immune dysfunction. The committee developed new risk assessment methods to examine this issue.

Although some risk assessment methods take into account changes in exposure with age, these models are not universally applied in practice. The committee explored the use of newer risk assessment methods that allow for changes in exposure and susceptibility with age. However, the committee found that sufficient data are not currently available to permit wide application of these methods.

RECOMMENDATIONS

On the basis of its findings, the committee recommends that certain changes be made in current regulatory practice. Most importantly, estimates of expected total exposure to pesticide residues should reflect the unique characteristics of the diets of infants and children and should account also for all nondietary intake of pesticides. Estimates of exposure should take into account the fact that not all crops are treated with pesticides that can be legally applied to those crops, and they should consider the effects of food processing and storage. Exposure estimates should recognize that pesticide residues may be present on more than one food commodity consumed by infants and children and that more than one pesticide may be present on one food sample. Lastly, determinations of safe levels of exposure should take into consideration the physiological factors that can place infants and children at greater risk of harm than adults.

• *Tolerances.* Tolerances for pesticide residues on commodities are currently established by the EPA under FIFRA and FFDCA. A tolerance concentration is defined under FFDCA as the maximum quantity of a pesticide residue allowable on a raw agricultural commodity (RAC) (FFDCA, Section 408) and in processed food when the pesticide concentrates during processing (FFDCA Section 409). Tolerance concentrations on RACs are based on the results of field trials conducted by pesticide manufacturers and are designed to reflect the highest residue concentrations likely under normal agricultural practice. More than 8,500 food tolerances for pesticides are currently listed in the Code of Federal Regulations (CFR). Approximately 8,350 of these tolerances are for residues on raw commodities (promulgated under section 408) and about 150 are for residues known to concentrate in processed foods (promulgated under section 409).

The determination of what might be a safe level of residue exposure is made by considering the results of toxicological studies of the pesticide's effects on animals and, when data are available, on humans. Both acute and chronic effects, including cancer, are considered, although acute effects are treated separately. These data are used to establish human exposure guidelines (i.e., a reference dose, RfD) against which one can compare the expected exposure. Exposure is a function of the amount and kind of foods consumed and the amount and identity of the residues in the foods (i.e., Theoretical Maximum Residue Contributions, TMRCs). If the TMRCs exceed the RfD, then anticipated residues are calculated for comparison with the proposed tolerance. The percent of crop acreage treated is also considered. If the anticipated residues exceed the RfD, then the proposed tolerance is rejected, and the manufacturer may recommend a new tolerance level.

Although tolerances establish enforceable legal limits for pesticide residues in food, they are not based primarily on health considerations, and they do not provide a good basis for inference about actual exposures of infants and children to pesticide residues in or on foods.

Tolerances constitute the only tool that EPA has under the law for controlling pesticide residues in food. **To ensure that infants and children are not exposed to unsafe levels of pesticide residues, the committee recommends that EPA modify its decision-making process for setting tolerances so that it is based more on health considerations than on agricultural practices. These changes should incorporate the use of improved estimates of exposure and more relevant toxicology, along with continued consideration of the requirements of agricultural production. As a result, human health considerations would be more fully reflected in tolerance levels. Children should be able to eat a healthful diet**

containing legal residues without encroaching on safety margins. This goal should be kept clear.

• *Toxicity testing.* The committee believes it is essential to develop toxicity testing procedures that specifically evaluate the vulnerability of infants and children. Testing must be performed during the developmental period in appropriate animal models, and the adverse effects that may become evident must be monitored over a lifetime. Of particular importance are tests for neurotoxicity and toxicity to the developing immune and reproductive systems. Extrapolation of toxicity data from adult and adolescent laboratory animals to young humans may be inaccurate. Careful attention to interspecies differences in pharmacokinetics and metabolism of pesticides and the relative ages at which organ systems mature is essential. It is also important to enhance understanding of developmental toxicity, especially in humans, during critical periods of postnatal development, including infancy and puberty.

• *Uncertainty factors.* For toxic effects other than cancer or heritable mutation, uncertainty factors are widely used to establish guidelines for human exposure on the basis of animal testing results. This is often done by dividing the no-observed-effect level (NOEL) found in animal tests by an uncertainty factor of 100-fold. This factor comprises two separate factors of 10-fold each: one allows for uncertainty in extrapolating data from animals to humans; the other accommodates variation within the human population. Although the committee believes that the latter uncertainty factor generally provides adequate protection for infants and children, this population subgroup may be uniquely susceptible to chemical exposures at particularly sensitive stages of development.

At present, to provide added protection during early development, a third uncertainty factor of 10 is applied to the NOEL to develop the RfD. This third 10-fold factor has been applied by the EPA and FDA whenever toxicity studies and metabolic/disposition studies have shown fetal developmental effects.

Because there exist specific periods of vulnerability during postnatal development, the committee recommends that an uncertainty factor up to the 10-fold factor traditionally used by EPA and FDA for fetal developmental toxicity should also be considered when there is evidence of postnatal developmental toxicity and when data from toxicity testing relative to children are incomplete. The committee wishes to emphasize that this is not a new, additional uncertainty factor but, rather, an extended application of a uncertainty factor now routinely used by the agencies for a narrower purpose.

In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption,

the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity.

• *Food consumption data.* The committee recommends that additional data on the food consumption patterns of infants and children be collected within narrow age groups. The available data indicate that infants and children consume much more of certain foods on a body weight basis than do adults. Because higher exposures can lead to higher risks, it is important to have accurate data on food consumption patterns for infants and children. At present, data are derived from relatively small samples and broad age groupings, making it difficult to draw conclusions about the food consumption patterns of infants and children. Because the composition of a child's diet changes dramatically from birth through childhood and adolescence to maturity, "market basket" food consumption surveys should include adequate samples of food consumption by children at 1-year intervals up to age 5, by children between the ages of 5 and 10 years, and by children between 11 and 18 years. Food consumption surveys should be conducted periodically to ascertain changes in consumption patterns over time.

• *Pesticide residue data.* To maximize the utility of pesticide residue data collected by various laboratories, the committee recommends the use of comparable analytical methods and standardized reporting procedures and the establishment of a computerized data base to collate data on pesticide residues generated by different laboratories. Reports on pesticide residue testing should describe the food commodity analyzed (whether processed or raw), the analytical methods used, the compounds for which tests were conducted, quality assurance and control procedures, and the limit of quantification of the tests. All findings should be reported, whether or not the residue sought is found.

–In its surveillance of pesticide residues, FDA should increase the frequency of sampling of the commodities most likely to be consumed by infants and children. The residue testing program should include all toxic forms of the pesticide, for example, its metabolites and degradation products.

–Food residue monitoring should target a special "market basket" survey focused toward the diets of infants and children.

–Pesticide field trials currently conducted by pesticide manufacturers in support of registration provide data on variation in residue concentrations associated with different rates and methods of application. Such data should be consulted to provide a basis for estimating potential maximum residue levels.

–More complete information is needed on the effects of food processing on levels of pesticides—both the parent compound and its metabolites—in specific food-chemical combinations potentially present in the diets of infants and children.

• *Risk assessment.* All exposures to pesticides—dietary and nondietary—need to be considered when evaluating the potential risks to infants and children. Nondietary environmental sources of exposure include air, dirt, indoor surfaces, lawns, and pets.

–Estimates of total dietary exposure should be refined to consider intake of multiple pesticides with a common toxic effect. Converting residues for each pesticide with a common mechanism of action to toxicity equivalence factors for one of the compounds would provide one approach to estimating total residue levels in toxicologically equivalent units.

–Consumption of pesticide residues in water is an important potential route of exposure. Risk assessment should include estimates of exposure to pesticides in drinking water and in water as a component of processed foods.

Given adequate data on food consumption and residues, the committee recommends the use of exposure distributions rather than single point data to characterize the likelihood of exposure to different concentrations of pesticide residues. The distribution of average daily exposure of individuals in the population of interest is most relevant for use in chronic toxicity risk assessment, and the distribution of individual daily intakes is recommended for evaluating acute toxicity. Ultimately, the collection of suitable data on the distribution of exposures to pesticides will permit an assessment of the proportion of the population that may be at risk.

Although the committee considers the use of exposure distributions to be more informative than point estimates of typical exposures, the data available to the committee did not always permit the distribution of exposures to be well characterized. Existing food consumption surveys generally involve relatively small numbers of infants and children, and food consumption data are collected for only a few days for each individual surveyed. Depending on the purpose for which they were originally collected, residue data may not reflect the actual distribution of pesticide residues in the food supply. Since residue data are not developed and reported in a consistent fashion, it is generally not possible to pool data sets derived from different surveys. Consequently, the committee recommends that guidelines be developed for consumption and residue data permitting characterization of distributions of dietary exposure to pesticides.

The committee identified important differences in susceptibility to the toxic effects of pesticides and exposure to pesticides in the diet with age.

For carcinogenic effects, the committee proposed new methods of cancer risk assessment designed to take such differences into account. Preliminary analyses conducted by the committee suggest that consideration of such differences can lead to lifetime estimates of cancer risk that can be higher or lower than estimates derived with methods based on constant exposure. However, underestimation of risk assuming constant exposure was limited to a factor of about 3- to 5-fold in all cases considered by the committee. Because these results are based on limited data and specific assumptions about the mechanisms by which carcinogenic effects are induced, the applicability of these conclusions under other conditions should be established.

Currently, most long-term laboratory studies of carcinogenesis and other chronic end points are based on protocols in which the level of exposure is held constant during the course of the study. To facilitate the application of risk assessment methods that allow for changes in exposure and susceptibility with age, it would be desirable to develop bioassay protocols that provide direct information on the relative contribution of exposures at different ages to lifetime risks. Although the committee does consider it necessary to develop special bioassay protocols for mandatory application in the regulation of pesticides, it would be useful to design special studies to provide information on the relative effects of exposures at different ages on lifetime cancer and other risks with selected chemical carcinogens.

In addition to pharmacodynamic models for cancer risk assessment, the committee recommends the development and application of physiologically based pharmacokinetic models that describe the unique features of infants and children. For example, differences in relative organ weights with age can be easily described in physiologic pharmacokinetic models; special compartments for the developing fetus may also be incorporated. Physiologically based pharmacokinetic models can be used to predict the dose of the proximate toxicant reaching target tissues, and may lead to more accurate estimates of risk.

In summary, better data on dietary exposure to pesticide residues should be combined with improved information on the potentially harmful effects of pesticides on infants and children. Risk assessment methods that enhance the ability to estimate the magnitude of these effects should be developed, along with appropriate toxicological tests for perinatal and childhood toxicity. The committee's recommendations support the need to improve methods for estimating exposure and for setting tolerances to safeguard the health of infants and children.

POSTHEARING QUESTIONS FOR DR. LANDRIGAN

SUBMITTED BY SENATOR LEAHY

Question 1. The NAS report recommended changes in food consumption and residue data collection procedures. At the same time, I understand that you are sharing with EPA, USDA, and FDA the computer programs for data analysis used by your committee. Would the use of these tools allow the Federal Government to improve risk assessment procedures—even using existing data while new data collection protocols are developed?

Answer. Our report does indeed recommend changes in data collection procedures for food consumption as well as for pesticide residues. Also we recommend improvements in the procedures used currently by the Federal agencies for risk assessment. To assist the agencies in enhancing their risk assessment efforts, we have provided copies to them of the computer programs that we used for data analysis in our report. Even before new consumption and residue data become available, these new approaches could improve the agencies' estimations of pesticide exposure in children and the resulting estimations of risk. We strongly encourage their use.

Question 2. During the hearing on June 29th, you stated that the chemical Alar and its metabolic breakdown product were "unquestionably human carcinogens." In light of the fact that young children are known to consume apple products, particularly apple juice, at levels much greater than the national average, did the use of Alar represent an unnecessary risk to infants and children, and has the removal of Alar from the market reduced the aggregate risk to children?

Answer. Our committee did not specifically address Alar as a case study, because Alar had largely disappeared from the U.S. domestic market when we began our work and was completely gone by the end of our analysis. Thus, the opinion on this matter that I offered at the hearing was my own and not the committee's. My opinion is based on the well-known fact that most hydrazine chemicals, including unsymmetrical dimethyl hydrazine (UDMH), a major metabolic breakdown product of Alar, are carcinogenic in laboratory animal studies. Indeed, UDMH itself has been shown to be a powerful carcinogen in well-conducted laboratory studies. Alar must therefore be regarded as though it were carcinogenic to humans and rated accordingly. The U.S. Environmental Protection Agency and the International Agency for Research on Cancer both treat Alar as a likely human carcinogen. It is my opinion that the removal of Alar from the market has unquestionably reduced children's risk of cancer.

Question 3. In testimony before the Senate Committee on Labor and Human Resources in 1991, Dr. John Wargo of Yale University suggested that we would only have to deal with a few pesticides to substantially reduce the risk to children. You appeared to agree with this conclusion in your testimony on June 29th. Based on the risk assessment calculations used in your report, please provide the committee with a list of the 10 or 20 pesticides that appear to pose the greatest risk to children.

Answer. The NAS committee specifically avoided naming "danger" chemicals or "danger" foods. Instead, our focus was to make recommendations to improve the methodologies now used by the Federal agencies for pesticide risk assessment. That said, however, it is indeed true that there are certain pesticides currently in use in the United States that convey very high risks of cancer, neurological toxicity, or toxicity to other organ systems. Respectfully, I suggest that the EPA, in consultation with FDA and USDA, is in a better position than our committee to provide you with the list you seek. I and other members of this NAS committee would be pleased to review the list that may be developed by EPA and to comment on the agency's choices and the rationale for them.

Question 4. In reforming our pesticide laws Congress must establish a standard that protects consumers, including infants and children, while still allowing EPA to take advantage of new scientific information. Would establishing a so-called "bright line" negligible risk standard help make EPA's tolerance setting procedures more protective for America's children? Would such a standard prevent EPA from employing and improving on new risk assessment methodologies?

Answer. Our committee did not consider details of the various approaches to pesticide regulation. That was not our mandate. Therefore, the opinion I offer here is my own.

The strength and the weakness of a bright line standard lies in its inflexibility. As a pediatrician and former public health officer, I believe that the bright line standard embodied in the Delaney Clause has done a good job of protecting the public's health, despite the criticisms that have been leveled at it. If it is replaced in new

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legislation, it should be replaced by language that is equally protective of child health, and it should not be given up lightly. Any new regulatory schemes should, of course, give agencies the ability to consider new data and new modalities of risk assessment as they become available.

Question 5. Among the conclusions in your report is that current pesticide regulations may allow for an unacceptable "front-end loading" of risk. In other words, children may accumulate a disproportionate share of their lifetime risks from exposure to chemical pesticides. Would a risk assessment standard that requires separate evaluations during the first 5 years of life, for example each year for the first 5 years, substantially reduce or eliminate this front-end loading problem?

Answer. Front-end loading of risk to children was of particular interest to our committee. Risks need to be specifically estimated for exposures occurring during each of the first 5 years of life to determine if there is the potential for accumulating excess risk during the early years. Regulatory procedures need to be structured in such a way as to reduce this risk. We specifically addressed this point in our analysis, and the equations necessary to study this question in detail are included in the computer software that we made available to EPA. A major conclusion of our report is that the EPA pay very close attention to this issue and that they take considerable pains to avoid front-end loading of risk upon children.

Question 6. Your report concludes that EPA toxicity testing requirements do not adequately evaluate the long-term effects of pesticide exposures in early life. The EPA, however, does attempt to assess the developmental effects of pesticides. Do the current developmental toxicity tests provide sufficient information on the vulnerability of infants and children?

Answer. The committee felt that current developmental toxicity tests do address some, but not all, of the issues of vulnerability of infants and children. Even with current testing, there are no good animal models to examine those vulnerabilities. That is the reason the committee recommended additional research in this important area. Further, the use of in utero tests should be conducted by EPA. They have been used by FDA, but not by EPA. Of particular importance are tests that involve early administration of pesticide chemicals coupled with lifetime followup of exposed animals.

Question 7. You emphasized the importance of considering the effects of multiple pesticide products and multiple routes of exposure when making risk assessments. Are there sufficient data to allow for an examination of the full range of possible exposure to environmental toxins? If not, what information is needed to effectively determine the risks associated with multiple pesticides on food and in the environment?

Answer. Currently, data are generally lacking to estimate the risks associated with exposure to multiple chemicals. The committee proposed an approach to this complex problem. However, to more accurately estimate risks, new residue and toxicity data on multiple chemical exposure will need to be developed.

Question 8. There is a great deal of concern about translating the results of animal studies, especially for carcinogens, to humans. Extrapolating differences between tests on young and adult animals further complicates this method. Are there proven, better alternatives for assessing risks to infants and children?

Answer. There are only limited methods available for estimating risks in children on the basis of animal studies. The report explains that new experimental methods will need to be developed in the future to enhance our ability to make such extrapolations. However, the committee does certainly accept wholeheartedly the basic premise that animal testing is predictive of similar effects in humans, and the committee must certainly recommend that toxicity testing in animals be continued and extended in order to protect the health of our Nation's children.

Question 9. So far, the food production industry appears willing to work with the findings of the committee to improve information on food consumption patterns and residue data. How could food producers and distributors improve their testing and reporting procedures to make that information more useful for Federal regulatory agencies and consumers?

Answer. We were very much encouraged by the positive response of the industry. Our report has provided a number of suggestions in this regard for the food industry. These include developing common methods for preparation, analysis, coding samples, data formats, and statistical analysis of test results. Currently, it is nearly impossible to compare different data bases because of the lack of uniformity.

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